From: s9(2)(a)
Sent: Thursday, 2 April 2020 4:53 pm
To: Nerissa Ramlall s9(2)(a)
Subject: RE: Phenelzine sulphate 97 units SOH Important

Hi Nerissa

To confirm LINK have scheduled for Friday 3rd April, tomorrow at 5pm. This time line is driven by the Australian team who are doing same at that time.

Hope to hear from you tomorrow, Ill take your call anytime as a key priority, always.

Kind Regards
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Thursday, 2 April 2020 4:48 PM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 97 units SOH Important

Hi s9(2)(a)

Thanks for sending this through.

Are you able to hold off from sending out the communications regarding the discontinuation of Nardil until we have had a chance to look into it further.

I will discuss this with the relevant therapeutic group manager and be in touch tomorrow.

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager
PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: +s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Thursday, 2 April 2020 3:30 PM
To: Nerissa Ramlall <s9(2)(a)
Subject: RE: Phenelzine sulphate 97 units SOH Important
Importance: High

Hi Nerissa

I am just in the middle of a total summary of projects for you in one email.

Nardil (phenelzine) was at the top. So here is the current situation:

- There have been 3 phenelzine products
    - 100310 Nardil (phenelzine sulphate) 15mg tab (x 100). The original registered brand that has been out of stock for some time. Out of Stock.
        1. Attached is a customer notification on this product which we are releasing to retail pharmacies and hospital pharmacies including wholesalers on Friday 3 at 5pm
    - 107050 Nardil ERFA (phenelzine sulfate) 15mg tab (x60). Which was the Section 29 supplied stock as an alternative to the above registered stock. Out of Stock.
    - 107851 Phenelzine sulphate (Lupin) 15mg tab (x60). It the second Section 29 product. Currently being sold.
        1. 97 units left in stock which is around one month, little less (CDC have one month also and haven't got other wholesalers at this stage)
        2. Our supplier has informed us that **no more stock is available. While we continue to search for stock we are not hopeful.**
        3. Our Australian company is also releasing this letter and notifying Clinical groups. We are also advising MedSafe on same day
    - Tablet appearance: Are you able to please confirm if the Lupin brand tablets look physically similar to the current product
        1. Our medinfo team are unable to provide this info at the moment but have asked.

We will continue to search everywhere but at this stage I have not confirmed supply other than above.

Ill keep in touch if this situation changes.

Kind Regards
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Thursday, 2 April 2020 3:07 PM
To: s9(2)(a)
Subject: FW: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

I hope you're well.

Just following up on the questions below. Are you able to please advise?

Many thanks,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nerissa Ramlall
Sent: Tuesday, 24 March 2020 11:56 AM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

Thanks for your email.

Were you able to advise on what the stock levels are at the wholesale level, do you anticipate that this is around one months' worth of stock?

I've also received a question from the therapeutic group manager regarding the Lupin alternative. Are you able to please confirm if the Lupin brand tablets look physically similar to the current product?

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

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s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Tuesday, 24 March 2020 11:18 AM
To: Nerissa Ramlall s9(2)(a)
Subject: Phenelzine sulphate 120 units SOH

Dear Nerissa

I will put this onto your weekly SOH update so that you can see the situation.
We still have 120 units SOH as per last week as no new purchase orders from wholesalers. I expect this to change this week.

Ill update you shortly.

s9(2)(a)

From: Nerissa Ramlall s9(2)(a)
Sent: Friday, 20 March 2020 11:31 AM
To: s9(2)(a)
Subject: Phenelzine sulphate Out of Scope

Hi s9(2)(a)

Thanks for your time on the phone yesterday.

Are you able to please look into the stock levels at wholesaler level and advise what these are? This would be useful for me to get a better understanding of the supply chain impact.

Out of Scope

[redacted]

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington

From: s9(2)(a)
Sent: Thursday, 2 April 2020 3:40 pm
To: Nerissa Ramlall s9(2)(a)
Subject: 107851 Phenelzine sulphate (Lupin) 15mg tab (x60) tablet appearance

Hi Nerissa

And here is our MedInfo response regarding the tablet appearance:

Short answer: Yes the tablets appear similar (Phenelzine Lupin and Nardil-ERFA (Canadian registered product; that we have been recently supplying).

Long answer:
We don't have any images of the actual tablets themselves. I did find some tablet images online but not from the company websites so please consider the table images below as a guide only.

I have copied the description of each tablet from the Phenlzine Lupin and Nardil-ERFA from the respective information leaflets below:

Phenelzine Lupin description 107851 Phenelzine sulphate (Lupin) 15mg tab (x60)

HOW SUPPLIED

Each Phenelzine Sulfate Tablets is orange, biconvex, film-coated tablets, debossed with "NL" on one side and "360" on the other side. Contains phenelzine sulfate equivalent to 15 mg of phenelzine base.

Nardil ERFA description

NARDIL is available as orange, biconvex, film-coated tablets engraved with "PD 270", in bottles of 60. Each tablet contains phenelzine sulfate, equivalent to 15 mg of phenelzine base.

Kind Regards
s9(2)(a)

From: s9(2)(a)
Sent: Thursday, 2 April 2020 4:22 pm
To: Nerissa Ramlall s9(2)(a) Craig Butler
s9(2)(a)
Subject: PHARMAC: update from Link Healthcare on Multiple product status

Hi Nerissa

As discussed I will try to update you each week on stock and products in discussion. If you would like others cc'd in and or removed from above list please advise. Ive put the name of the person at PHARMAC who has been most involved.

Please see notes as follows and advise if any thing else is required to go on this list:

- Phenelzine (Nardil)-as advised under separate email sent recently

- Nerissa Ramlall <Balance of document is out of scope>
- There have been 3 phenelzine products

- 100310 Nardil (phenelzine sulphate) 15mg tab (x 100). The original registered brand that has been out of stock for some time. Out of Stock.

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2. 97 units left in stock which is around one month, little less (CDC have one month also and haven't got other wholesalers at this stage)
3. Our supplier has informed us that **no more stock is available. While we continue to search for stock we are not hopeful.**
4. Our Australian company is also releasing this letter and notifying Clinical groups. We are also advising MedSafe on same day

- Tablet appearance: Are you able to please confirm if the Lupin brand tablets look physically similar to the current product

5. Email sent with reply

- We will continue to search everywhere but at this stage I have not confirmed supply other than above.

balance of document is out of scope

LINK
A CLINIGEN COMPANY

PO Box 718
Mona Vale
NSW 1660
Australia

+61 2 8401 9777
+61 2 8401 9788
info@linkhealthcare.com.au

March 2020

Important Announcement: Nardil Discontinuation

NARDIL phenelzine 15mg (as sulfate) tablet bottle

Dear Valued Customer,

This notification is to inform you of the discontinuation of **NARDIL (phenelzine) tablets**.

Due to situations beyond our control, the manufacturing site for NARDIL phenelzine 15mg (as sulfate) tablet bottle has closed. Link had arranged supply of an unregistered alternative product, Canadian registered NARDIL ERFA phenelzine 15mg tablets USP, however we are now informed that this product will not be available throughout 2020.

Despite our continued attempts, Link have not been able to secure adequate alternative options to cover the anticipated phenelzine requirements throughout 2020.

Patients are advised to discuss alternative treatment options with their Doctor as soon as possible.

We thank you for your understanding during this unfortunate circumstance.

Kind regards,

Amanda Whiteman
Business Unit Manager

LHCNZ_NAR03_Mar20

LINK
A CLINIGEN COMPANY

PO Box 718
Mona Vale
NSW 1660
Australia

+61 2 8401 9777
+61 2 8401 9788
info@linkhealthcare.com.au

March 2020

Important Announcement: Nardil Discontinuation

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Despite our continued attempts, Link have not been able to secure adequate alternative options to cover the anticipated phenelzine requirements throughout 2020.

Patients are advised to discuss alternative treatment options with their Doctor as soon as possible.

We thank you for your understanding during this unfortunate circumstance.

Kind regards,

Amanda Whiteman
Business Unit Manager

Nardil data sheet can be located at: www.medsafe.govt.nz/profs/Datasheet/n/nardiltab.pdf

LHCNZ_NAR03_Mar20

From: Nerissa Ramlall
Sent: Thursday, 2 April 2020 3:07 pm
To: Link Healthcare s9(2)(a)
Subject: FW: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

I hope you're well.

Just following up on the questions below. Are you able to please advise?

Many thanks,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: +s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nerissa Ramlall
Sent: Tuesday, 24 March 2020 11:56 AM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

Thanks for your email.

Were you able to advise on what the stock levels are at the wholesale level, do you anticipate that this is around one months' worth of stock?

I've also received a question from the therapeutic group manager regarding the Lupin alternative. Are you able to please confirm if the Lupin brand tablets look physically similar to the current product?

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

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From: s9(2)(a)
Sent: Tuesday, 24 March 2020 11:18 AM
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Dear Nerissa

I will put this onto your weekly SOH update so that you can see the situation.
We still have 120 units SOH as per last week as no new purchase orders from wholesalers. I expect this to change this week.

Ill update you shortly.

s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)>
Sent: Friday, 20 March 2020 11:31 AM
To: s9(2)(a)>
Subject: Phenelzine sulphate Out of Scope

Hi s9(2)(a),

Thanks for your time on the phone yesterday.

Are you able to please look into the stock levels at wholesaler level and advise what these are? This would be useful for me to get a better understanding of the supply chain impact.

Out of Scope

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager
PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: +s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Sarita Von Afehlt <s9(2)(a)
Sent: Monday, 23 March 2020 8:19 am
To: Nerissa Ramlall <s9(2)(a)
Cc: Peter Yoo s9(2)(a)
Subject: RE: IMPORTANT: Nardil possible discontinuation and in addition current possible supply issue

Hi Nerissa

[copying in Peter just so he knows I've replied to this – he isn't expected to do anything when I leave as Adam will be the interim point of contact for my 3 TGs]

The packaging of the Lupin product looks fine and it's the same salt and strength. Do we know if the tablets themselves look physically similar to the current product?

Given there may be ongoing supply issues with phenelzine, we should add a "no new patients" restriction to phenelzine in both Section B & Section H. Can you please do this when you list the Lupin s29 brand? See below for wording used for dosulepin. Phenelzine is an older style antidepressant with limited but niche use so I think it will be okay to add this restriction.

DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Subsidy by endorsement

a) Safety medicine; prescriber may determine dispensing frequency
b) Subsidy by endorsement – Subsidised for patients who were taking dosulepin [dothiepin] hydrochloride prior to 1 June 2019 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of dosulepin [dothiepin] hydrochloride.

Tab 75 mg	11.19	100	✔ **Dopress**
Cap 25 mg	7.83	50	✔ **Dosulepin Mylan** S29

In order to answer your question about an out of cycle listing, I'd need to know what the usage is (volume of product and approx. no. of patients) for phenelzine. Can you provide me that info please?

Many thanks
Sarita

s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)>
Sent: Friday, March 20, 2020 10:15 AM
To: Sarita Von Afehlt s9(2)(a)>
Cc: Peter Yoo <s9(2)(a)
Subject: FW: IMPORTANT: Nardil possible discontinuation and in addition current possible supply issue

Hi Sarita,

Link supplies Phenelzine sulphate (Nardil) tab 15 mg under the terms of a 2006 listing agreement.

There is an ongoing supply issue with Link's registered product (recall) and it has sourced an alternative s29. The s29 Nardil product is now unable to be supplied until early 2021. Link had 2 months SOH (with one month stock at wholesalers).

Link has since advised that demand has increased overnight due to wholesalers/pharmacist stockpiling and now have about 5 weeks worth of SOH.

Link has identified an alternative, Lupin. The images and PI is attached.

Link has requested to list this prior to 1 May 2020 (this would be out of cycle), as demand is increasing significantly. I'm asking Link to find out the stock levels within the supply chain for us to get a better understanding of the situation.

Link also flagged that it may provide notice of discontinuation in the near future.

Questions:

1. Is the s29 Lupin product suitable to list?
2. If the overall stock levels in the chain are low, would an out of cycle listing be necessary?

Thanks,

N

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Monday, 16 March 2020 7:27 PM
To: Brian Roulston <s9(2)(a)>; Nerissa Ramlall
s9(2)(a)
Subject: IMPORTANT: Nardil possible discontinuation and in addition current possible supply issue

Dear Brian and Nerissa

As you know, we have been supplying an alternative Section 29 product for Nardil (as the Registered product is unavailable) and now the alternative product supplier is also unable to supply more stock at least until early 2021. So supply is uncertain.

We have another alternative Lupin phenelzine tablets available right now, but the ongoing supply of this second alternative product is also not certain. Pack pictures and PI attached.

We are exploring options right now but while it is not yet confirmed we may have to **discontinue supply**, in a few months.

Currently there are 2 mths stock on hand/3 with wholesaler stock and maybe able to get some more of the 2nd alternative TBC.

I'm writing to you before we have final information to confirm to give you as much time as possible to review with TGM and clinical team. Our Australian Medical team are currently working on options and further communications that I will forward asap. We will work with you and provide as much information as possible as it becomes available.

Please let me know if you require any information or additional actions. Will be in touch.

s9(2)(a)

s9(2)(a)

Manager New Zealand (FACBS, MSc, BSc)

Link (A Clinigen Company)

t. +64 (9) 358 7146 | m. s9(2)(a)

e. s9(2)(a)

w. www.clinigengroup.com

From: s9(2)(a)
Sent: Monday, 16 March 2020 7:27 pm
To: Brian Roulston s9(2)(a) Nerissa Ramlall
s9(2)(a)
Subject: IMPORTANT: Nardil possible discontinuation and in addition current possible supply issue

Dear Brian and Nerissa

As you know, we have been supplying an alternative Section 29 product for Nardil (as the Registered product is unavailable) and now the alternative product supplier is also unable to supply more stock at least until early 2021. So supply is uncertain.

We have another alternative Lupin phenelzine tablets available right now, but the ongoing supply of this second alternative product is also not certain. Pack pictures and PI attached.

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I'm writing to you before we have final information to confirm to give you as much time as possible to review with TGM and clinical team. Our Australian Medical team are currently working on options and further communications that I will forward asap. We will work with you and provide as much information as possible as it becomes available.

Please let me know if you require any information or additional actions. Will be in touch.

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Manager New Zealand (FACBS, MSc, BSc)

Link (A Clinigen Company)
t. +64 (9) 358 7146 | s9(2)(a)
e. s9(2)(a)
w. www.clinigengroup.com

PHENELZINE SULFATE- phenelzine sulfate tablet
Lupin Pharmaceuticals,Inc.

PHENELZINE SULFATE TABLETS, USP

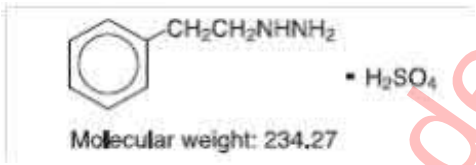
Rx Only

Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Phenelzine Sulfate Tablets or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Phenelzine Sulfate Tablets is not approved for use in pediatric patients. (See Warnings: Clinical Worsening and Suicide Risk, Precautions: Information for Patients, and Precautions: Pediatric Use)

DESCRIPTION

Phenelzine Sulfate Tablets, USP (phenelzine sulfate) is a potent inhibitor of monoamine oxidase (MAO). Phenelzine sulfate is a hydrazine derivative. It has a molecular weight of 234.27 and is chemically described as $C_8H_{12}N_2 \cdot H_2SO_4$. Its chemical structure is shown below:



Each Phenelzine Sulfate Tablets film-coated for oral administration contains phenelzine sulfate equivalent to 15 mg of phenelzine base and the following inactive ingredients: mannitol, USP; colloidal silicon dioxide, NF; povidone, USP; edetate disodium, USP; magnesium stearate, NF; purified water, USP; polyvinyl alcohol part hydrolyzed USP, polyethylene glycol-3350 NF, FD&C yellow # 6, talc USP and titanium dioxide USP.

CLINICAL PHARMACOLOGY

Monoamine oxidase is a complex enzyme system, widely distributed throughout the body. Drugs that inhibit monoamine oxidase in the laboratory are associated with a number of clinical effects. Thus, it is unknown whether MAO inhibition per se, other pharmacologic actions, or an interaction of both is responsible for the clinical effects observed. Therefore, the physician should become familiar with all the effects produced by drugs of this class.

Pharmacokinetics

Absorption

Following a single 30 mg dose of Phenelzine Sulfate Tablets (2 × 15 mg tablets), a mean peak plasma concentration (C_{max}) of 19.8 ng/mL occurred at a time (T_{max}) of 43 minutes postdose.

Metabolism

Phenelzine Sulfate Tablets is extensively metabolized, primarily by oxidation via monoamine oxidase. After oral administration of $^{13}C_6$-phenelzine, 73% of the administered dose was recovered in urine as phenylacetic acid and parahydroxyphenylacetic acid within 96 hours. Acetylation to N^2-acetylphenelzine is a minor pathway.

Elimination

The mean elimination half-life after a single 30 mg dose is 11.6 hours. Multiple dose pharmacokinetics have not been studied in man.

INDICATIONS AND USAGE

Phenelzine Sulfate Tablets, USP has been found to be effective in depressed patients clinically characterized as "atypical," "nonendogenous," or "neurotic." These patients often have mixed anxiety and depression and phobic or hypochondriacal features. There is less conclusive evidence of its usefulness with severely depressed patients with endogenous features.

Phenelzine Sulfate Tablets should rarely be the first antidepressant drug used. Rather, it is more suitable for use with patients who have failed to respond to the drugs more commonly used for these conditions.

CONTRAINDICATIONS

Phenelzine Sulfate Tablets should not be used in patients who are hypersensitive to the drug or its ingredients, with pheochromocytoma, congestive heart failure, severe renal impairment or renal disease, a history of liver disease, or abnormal liver function tests.

The potentiation of sympathomimetic substances and related compounds by MAO inhibitors may result in hypertensive crises (see WARNINGS). Therefore, patients being treated with Phenelzine Sulfate Tablets should not take sympathomimetic drugs (including amphetamines, cocaine, methylphenidate, dopamine, epinephrine, and norepinephrine) or related compounds (including methyldopa, L-dopa, L-tryptophan, L-tyrosine, and phenylalanine). Hypertensive crises during Phenelzine Sulfate Tablets therapy may also be caused by the ingestion of foods with a high concentration of tyramine or dopamine. Therefore, patients being treated with Phenelzine Sulfate Tablets should avoid high protein food that has undergone protein breakdown by aging, fermentation, pickling, smoking, or bacterial contamination. Patients should also avoid cheeses (especially aged varieties), pickled herring, beer, wine, liver, yeast extract (including brewer's yeast in large quantities), dry sausage (including Genoa salami, hard salami, pepperoni, and Lebanon bologna), pods of broad beans (fava beans), and yogurt. Excessive amounts of caffeine and chocolate may also cause hypertensive reactions.

Phenelzine Sulfate Tablets should not be used in combination with dextromethorphan or with CNS depressants such as alcohol and certain narcotics. Excitation, seizures, delirium, hyperpyrexia, circulatory collapse, coma, and death have been reported in patients receiving MAOI therapy who have been given a single dose of meperidine. Phenelzine Sulfate Tablets should not be administered together with or in rapid succession to other MAO inhibitors because HYPERTENSIVE CRISES and convulsive seizures, fever, marked sweating, excitation, delirium, tremor, coma, and circulatory collapse may occur.

Concomitant use with meperidine is contraindicated (see WARNINGS).

A List of MAO Inhibitors by Generic Name Follows:

pargyline hydrochloride

pargyline hydrochloride and methylclothiazide

furazolidone

isocarboxazid

procarbazine

tranylcypromine

Phenelzine Sulfate Tablets should also not be used in combination with buspirone HCl, since several cases of elevated blood pressure have been reported in patients taking MAO inhibitors who were then given buspirone HCl. At least 14 days should elapse between the discontinuation of Phenelzine Sulfate Tablets and the institution of another antidepressant or buspirone HCl, or the discontinuation of another MAO inhibitor and the institution of Phenelzine Sulfate Tablets.

There have been reports of serious reactions (including hyperthermia, rigidity, myoclonic movements and death) when serotoninergic drugs (e.g., dexfenfluramine, fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, venlafaxine) have been combined with an MAO inhibitor. Therefore, the concomitant use of Phenelzine Sulfate Tablets with serotoninergic agents is contraindicated (see PRECAUTIONS Drug Interactions). At least 14 days should elapse between the discontinuation of an MAO inhibitor and the start of a serotonin re-uptake inhibitor or vice-versa, with the exception of fluoxetine. Allow at least five weeks between discontinuation of fluoxetine and initiation of Phenelzine Sulfate Tablets and at least 14 days between discontinuation of Phenelzine Sulfate Tablets and initiation of fluoxetine, or other serotoninergic agents. Before initiating Phenelzine Sulfate Tablets after using other serotoninergic agents, a sufficient amount of time must be allowed for clearance of the serotoninergic agent and its active metabolites.

The combination of MAO inhibitors and tryptophan has been reported to cause behavioral and neurologic syndromes including disorientation, confusion, amnesia, delirium, agitation, hypomanic signs, ataxia, myoclonus, hyperreflexia, shivering, ocular oscillations, and Babinski signs.

The concurrent administration of an MAO inhibitor and bupropion hydrochloride (Wellbutrin®) is contraindicated. At least 14 days should elapse between discontinuation of an MAO inhibitor and initiation of treatment with bupropion hydrochloride.

Patients taking Phenelzine Sulfate Tablets should not undergo elective surgery requiring general anesthesia. Also, they should not be given cocaine or local anesthesia containing sympathomimetic vasoconstrictors. The possible combined hypotensive effects of Phenelzine Sulfate Tablets and spinal anesthesia should be kept in mind. Phenelzine Sulfate Tablets should be discontinued at least 10 days prior to elective surgery.

MAO inhibitors, including Phenelzine Sulfate Tablets, are contraindicated in patients receiving guanethidine.

WARNINGS

Clinical Worsening and Suicide Risk

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment.

Pooled analyses of short term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18–24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.

The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1.

Table 1

Age Range	**Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated**
	Increases Compared to Placebo
<18	14 additional cases
18–24	5 additional cases
	Decreases Compared to Placebo
25–64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the

need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Phenelzine Sulfate Tablets should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Screening Patients for Bipolar Disorder

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Phenelzine Sulfate Tablets are not approved for use in treating bipolar depression.

It should be noted that Phenelzine Sulfate Tablets are not approved for use in treating any indications in the pediatric population.

Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs including Phenelzine Sulfate Tablets may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

The most serious reactions to Phenelzine Sulfate Tablets involve changes in blood pressure.

Hypertensive Crises

The most important reaction associated with Phenelzine Sulfate Tablets administration is the occurrence of hypertensive crises, which have sometimes been fatal.

These crises are characterized by some or all of the following symptoms: occipital headache which may radiate frontally, palpitation, neck stiffness or soreness, nausea, vomiting, sweating (sometimes with fever and sometimes with cold, clammy skin), dilated pupils, and photophobia. Either tachycardia or bradycardia may be present and can be associated with constricting chest pain.

NOTE: Intracranial bleeding has been reported in association with the increase in blood pressure.

Blood pressure should be observed frequently to detect evidence of any pressor response in all patients receiving Phenelzine Sulfate Tablets. Therapy should be discontinued immediately upon the occurrence of palpitation or frequent headaches during therapy.

Recommended treatment in hypertensive crisis

If a hypertensive crisis occurs, Phenelzine Sulfate Tablets should be discontinued immediately and therapy to lower blood pressure should be instituted immediately. On the basis of present evidence, phentolamine is recommended. (The dosage reported for phentolamine is 5 mg intravenously.) Care should be taken to administer this drug slowly in order to avoid producing an excessive hypotensive effect. Fever should be managed by means of external cooling.

Warning to the Patient

All patients should be warned that the following foods, beverages, and medications must be avoided while taking Phenelzine Sulfate Tablets, and for two weeks after discontinuing use.

Foods and Beverages To Avoid

Meat and Fish

Pickled herring

Liver

Dry sausage (including Genoa salami, hard salami, pepperoni, and Lebanon bologna)

Vegetables

Broad bean pods (fava bean pods)

Sauerkraut

Dairy Products

Cheese (cottage cheese and cream cheese are allowed)

Yogurt

Beverages

Beer and wine

Alcohol-free and reduced-alcohol beer and wine products

Miscellaneous

Yeast extract (including brewer's yeast in large quantities)

Meat extract

Excessive amounts of chocolate and caffeine

Also, any spoiled or improperly refrigerated, handled, or stored protein-rich foods such as meats, fish, and dairy products, including foods that may have undergone protein changes by aging, pickling, fermentation, or smoking to improve flavor should be avoided.

OTC Medications To Avoid

Cold and cough preparations (including those containing dextromethorphan)

Nasal decongestants (tablets, drops, or spray)

Hay-fever medications

Sinus medications

Asthma inhalant medications

Antiappetite medicines

Weight-reducing preparations

"Pep" pills

L-tryptophan containing preparations

Also, certain prescription drugs should be avoided. Therefore, patients under the care of another physician or dentist should inform him/her that they are taking Phenelzine Sulfate Tablets.

Patients should be warned that the use of the above foods, beverages, or medications may cause a reaction characterized by headache and other serious symptoms due to a rise in blood pressure, with the exception of dextromethorphan which may cause reactions similar to those seen with meperidine. Also, there has been a report of an interaction between Phenelzine Sulfate Tablets and dextromethorphan (ingested as a lozenge) causing drowsiness and bizarre behavior.

Patients should be instructed to report promptly the occurrence of headache or other unusual symptoms.

Concomitant Use with Dibenzazepine Derivative Drugs

If the decision is made to administer Phenelzine Sulfate Tablets concurrently with other antidepressant

drugs, or within less than 10 days after discontinuation of antidepressant therapy, the patient should be cautioned by the physician regarding the possibility of adverse drug interaction.

A List of Dibenzazepine Derivative Drugs by Generic Name Follows:

nortriptyline hydrochloride

amitriptyline hydrochloride

perphenazine and amitriptyline hydrochloride

clomipramine hydrochloride

desipramine hydrochloride

imipramine hydrochloride

doxepin

carbamazepine

cyclobenzaprine HCl

amoxapine

maprotiline HCl

trimipramine maleate

protriptyline HCl

mirtazapine

Phenelzine Sulfate Tablets should be used with caution in combination with antihypertensive drugs, including thiazide diuretics and β-blockers, since exaggerated hypotensive effects may result.

Use in Pregnancy

The safe use of Phenelzine Sulfate Tablets during pregnancy or lactation has not been established. The potential benefit of this drug, if used during pregnancy, lactation, or in women of childbearing age, should be weighed against the possible hazard to the mother or fetus.

Doses of Phenelzine Sulfate Tablets in pregnant mice well exceeding the maximum recommended human dose have caused a significant decrease in the number of viable offspring per mouse. In addition, the growth of young dogs and rats has been retarded by doses exceeding the maximum human dose.

PRECAUTIONS

Information for Patients

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Phenelzine Sulfate Tablets and should counsel them in its appropriate use. A patient Medication Guide about "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicidal Thoughts or Actions" is available for Phenelzine Sulfate Tablets. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.

Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Phenelzine Sulfate Tablets.

Patients should be advised that taking Phenelzine Sulfate Tablets can cause mild pupillary dilation, which in susceptible individuals, can lead to an episode of angle-closure glaucoma. Pre-existing

glaucoma is almost always open-angle glaucoma because angle-closure glaucoma, when diagnosed, can be treated definitively with iridectomy. Open-angle glaucoma is not a risk factor for angle closure glaucoma. Patients may wish to be examined to determine whether they are susceptible to angle closure, and have a prophylactic procedure (e.g., iridectomy), if they are susceptible.

Clinical Worsening and Suicide Risk

Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS—Clinical Worsening and Suicide Risk)

Anyone considering the use of Phenelzine Sulfate Tablets in a child or adolescent must balance the potential risks with the clinical need.

Phenelzine Sulfate Tablets, as with other hydrazine derivatives, has been reported to induce pulmonary and vascular tumors in an uncontrolled lifetime study in mice.

In depressed patients, the possibility of suicide should always be considered and adequate precautions taken. It is recommended that careful observations of patients undergoing Phenelzine Sulfate Tablets treatment be maintained until control of depression is achieved. If necessary, additional measures (ECT, hospitalization, etc) should be instituted.

All patients undergoing treatment with Phenelzine Sulfate Tablets should be closely followed for symptoms of postural hypotension. Hypotensive side effects have occurred in hypertensive as well as normotensive and hypotensive patients. Blood pressure usually returns to pretreatment levels rapidly when the drug is discontinued or the dosage is reduced.

Because the effect of Phenelzine Sulfate Tablets on the convulsive threshold may be variable, adequate precautions should be taken when treating epileptic patients.

Of the more severe side effects that have been reported with any consistency, hypomania has been the most common. This reaction has been largely limited to patients in whom disorders characterized by hyperkinetic symptoms coexist with, but are obscured by, depressive affect; hypomania usually appeared as depression improved. If agitation is present, it may be increased with Phenelzine Sulfate Tablets.

Hypomania and agitation have also been reported at higher than recommended doses or following long-term therapy.

Phenelzine Sulfate Tablets may cause excessive stimulation in schizophrenic patients; in manic-depressive states it may result in a swing from a depressive to a manic phase.

Phenelzine Sulfate Tablets should be used with caution in diabetes mellitus; increased insulin sensitivity may occur. Requirements for insulin or oral hypoglycemics may be decreased.

MAO inhibitors, including Phenelzine Sulfate Tablets, potentiate hexobarbital hypnosis in animals. Therefore, barbiturates should be given at a reduced dose with Phenelzine Sulfate Tablets.

MAO inhibitors inhibit the destruction of serotonin and norepinephrine, which are believed to be

released from tissue stores by rauwolfia alkaloids. Accordingly, caution should be exercised when rauwolfia is used concomitantly with an MAO inhibitor, including Phenelzine Sulfate Tablets.

There is conflicting evidence as to whether or not MAO inhibitors affect glucose metabolism or potentiate hypoglycemic agents. This should be kept in mind if Phenelzine Sulfate Tablets is administered to diabetics.

Drug Interactions

In patients receiving nonselective monoamine oxidase (MAO) inhibitors in combination with serotoninergic agents (e.g., dexfenfluramine, fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, venlafaxine) there have been reports of serious, sometimes fatal, reactions. Because Phenelzine Sulfate Tablets is a monoamine oxidase (MAO) inhibitor, Phenelzine Sulfate Tablets should not be used concomitantly with a serotoninergic agent (See CONTRAINDICATIONS).

Administration of guanethidine to patients receiving an MAO inhibitor can produce moderate to severe hypertension due to release of catecholamines. At least two weeks should elapse between withdrawal of the MAO inhibitor and the initiation of guanethidine. (see CONTRAINDICATIONS)

Geriatric Use

Clinical studies of Phenelzine Sulfate Tablets did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Phenelzine Sulfate Tablets is a potent inhibitor of monoamine oxidase. Because this enzyme is widely distributed throughout the body, diverse pharmacologic effects can be expected to occur. When they occur, such effects tend to be mild or moderate in severity (see below), often subside as treatment continues, and can be minimized by adjusting dosage; rarely is it necessary to institute counteracting measures or to discontinue Phenelzine Sulfate Tablets.

Common side effects include:

Nervous System —Dizziness, headache, drowsiness, sleep disturbances (including insomnia and hypersomnia), fatigue, weakness, tremors, twitching, myoclonic movements, hyperreflexia.

Gastrointestinal—Constipation, dry mouth, gastrointestinal disturbances, elevated serum transaminases (without accompanying signs and symptoms).

Metabolic —Weight gain.

Cardiovascular —Postural hypotension, edema.

Genitourinary—Sexual disturbances, eg, anorgasmia and ejaculatory disturbances and impotence.

Less common mild to moderate side effects (some of which have been reported in a single patient or by a single physician) include:

Nervous System —Jitteriness, palilalia, euphoria, nystagmus, paresthesias.

Genitourinary—Urinary retention.

Metabolic —Hypernatremia.

Dermatologic —Pruritus, skin rash, sweating.

Special Senses —Blurred vision, angle-closure glaucoma.

Although reported less frequently, and sometimes only once, additional severe side effects include:

Nervous System—Ataxia, shock-like coma, toxic delirium, manic reaction, convulsions, acute anxiety reaction, precipitation of schizophrenia, transient respiratory and cardiovascular depression following ECT.

Gastrointestinal—To date, fatal progressive necrotizing hepatocellular damage has been reported in very few patients. Reversible jaundice.

Hematologic —Leukopenia.

Immunologic—Lupus-like syndrome

Metabolic—Hypermetabolic syndrome (which may include, but is not limited to, hyperpyrexia, tachycardia, tachypnea, muscular rigidity, elevated CK levels, metabolic acidosis, hypoxia, coma and may resemble an overdose).

Respiratory—Edema of the glottis.

General—Fever associated with increased muscle tone.

Withdrawal may be associated with nausea, vomiting, and malaise.

An uncommon withdrawal syndrome following abrupt withdrawal of Phenelzine Sulfate Tablets has been infrequently reported. Signs and symptoms of this syndrome generally commence 24 to 72 hours after drug discontinuation and may range from vivid nightmares with agitation to frank psychosis and convulsions. This syndrome generally responds to reinstitution of low-dose Phenelzine Sulfate Tablets therapy followed by cautious downward titration and discontinuation.

DOSAGE AND ADMINISTRATION

Initial dose

The usual starting dose of Phenelzine Sulfate Tablets is one tablet (15 mg) three times a day.

Early phase treatment

Dosage should be increased to at least 60 mg per day at a fairly rapid pace consistent with patient tolerance. It may be necessary to increase dosage up to 90 mg per day to obtain sufficient MAO inhibition. Many patients do not show a clinical response until treatment at 60 mg has been continued for at least 4 weeks.

Maintenance dose

After maximum benefit from Phenelzine Sulfate Tablets is achieved, dosage should be reduced slowly over several weeks. Maintenance dose may be as low as one tablet, 15 mg, a day or every other day, and should be continued for as long as is required.

OVERDOSAGE

Note—For management of *hypertensive crises* see WARNINGS section.

Accidental or intentional overdosage may be more common in patients who are depressed. It should be remembered that multiple drugs and/or alcohol may have been ingested.

Depending on the amount of overdosage with Phenelzine Sulfate Tablets, a varying and mixed clinical picture may develop, including signs and symptoms of central nervous system and cardiovascular stimulation and/or depression. Signs and symptoms may be absent or minimal during the initial 12-hour period following ingestion and may develop slowly thereafter, reaching a maximum in 24–48 hours. Death has been reported following overdosage. Therefore, immediate hospitalization, with continuous patient observation and monitoring throughout this period, is essential.

Signs and symptoms of overdosage may include, alone or in combination, any of the following: drowsiness, dizziness, faintness, irritability, hyperactivity, agitation, severe headache, hallucinations, trismus, opisthotonus, rigidity, convulsions, and coma; rapid and irregular pulse, hypertension, hypotension, and vascular collapse; precordial pain, respiratory depression and failure, hyperpyrexia, diaphoresis, and cool, clammy skin.

Treatment

Intensive symptomatic and supportive treatment may be required. Induction of emesis or gastric lavage with instillation of charcoal slurry may be helpful in early poisoning, provided the airway has been protected against aspiration. Signs and symptoms of central nervous system stimulation, including convulsions, should be treated with diazepam, given slowly intravenously. Phenothiazine derivatives and central nervous system stimulants should be avoided. Hypotension and vascular collapse should be treated with intravenous fluids and, if necessary, blood pressure titration with an intravenous infusion of dilute pressor agent. It should be noted that adrenergic agents may produce a markedly increased pressor response.

Respiration should be supported by appropriate measures, including management of the airway, use of supplemental oxygen, and mechanical ventilatory assistance, as required.

Body temperature should be monitored closely. Intensive management of hyperpyrexia may be required. Maintenance of fluid and electrolyte balance is essential.

There are no data on the lethal dose in man. The pathophysiologic effects of massive overdosage may persist for several days, since the drug acts by inhibiting physiologic enzyme systems. With symptomatic and supportive measures, recovery from *mild* overdosage may be expected within 3 to 4 days.

Hemodialysis, peritoneal dialysis, and charcoal hemoperfusion may be of value in massive overdosage, but sufficient data are not available to recommend their routine use in these cases.

Toxic blood levels of phenelzine have not been established, and assay methods are not practical for clinical or toxicological use.

HOW SUPPLIED

Each Phenelzine Sulfate Tablets is orange, biconvex, film-coated tablets, debossed with "NL" on one side and "360" on the other side. Contains phenelzine sulfate equivalent to 15 mg of phenelzine base.

NDC 43386-360-21. Bottle of 60

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Preserve in tight containers, protected from heat and light.

Rx only

Manufactured by:

Novel Laboratories Inc,

Somerset, NJ 08873

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, MD 21202

PI3600000204

Rev. 05/2016

MEDICATION GUIDE

Antidepressant Medicines, Depression and other Serious Mental Illnesses, And Suicidal Thoughts or Actions

Read the Medication Guide that comes with you or your family member's antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines.
Talk to your, or your family member's, healthcare provider about:

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illness

What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?

1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**

- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- an extreme increase in activity and talking (mania)
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- other unusual changes in behavior or mood
- **Visual problems:** eye pain, changes in vision, swelling or redness in or around the eye.

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Visual problems:** Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to

discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.

- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.
- Call your doctor for medical advice about side effects, You may report side effects to FDA at 1-800- FDA-1088

Medication Guide revised on May 2016

This Medication Guide has been approved by the U.S. Food and Drug Administration for all antidepressants.

Manufactured by:

Novel Laboratories, Inc.

Somerset, NJ 08873

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, MD 21202

PI3600000204

Rev. 05/2016

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Phenelzine Sulfate Tablets, USP

NDC 43386-360-21

60 Tablets

PHENELZINE SULFATE

phenelzine sulfate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43386-360
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENELZINE SULFATE (UNII: 2681D7P965) (PHENELZINE - UNII:O408N561GF)	PHENELZINE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	NL;360
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43386-360-21	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/14/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200181	12/14/2010	

Labeler - Lupin Pharmaceuticals,Inc. (089153071)

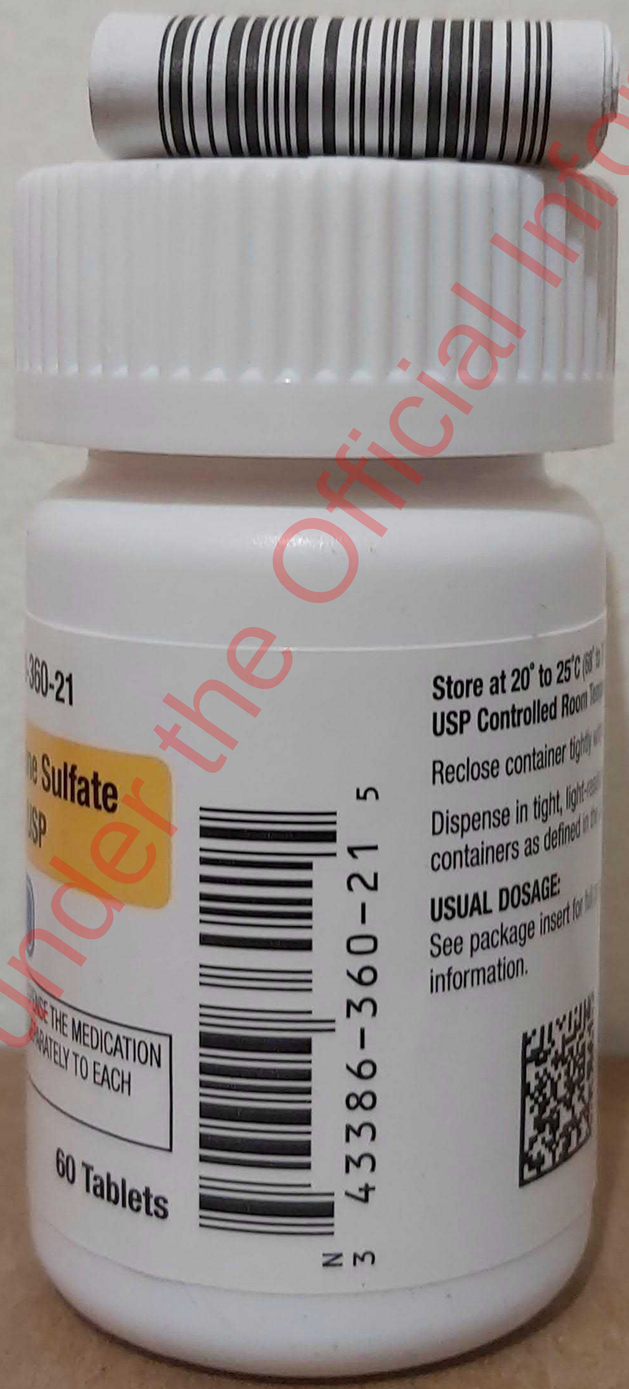
Registrant - Novel Laboratories, Inc. (793518643)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	ANALYSIS(43386-360) , MANUFACTURE(43386-360) , PACK(43386-360)

Revised: 9/2017

Lupin Pharmaceuticals,Inc.



From: s9(2)(a)
Sent: Monday, 4 May 2020 4:39 pm
To: Nerissa Ramlall <s9(2)(a)
Subject: MedSafe Discontinuation Notice Confirmed Action: Updated TPDR - Nardil (TT50-0702/1)

Hi Nerissa

Copy for your reference.
Nardil discontinued on MedSafe website.

Thanks
s9(2)(a)

From: s9(2)(a)
Sent: Monday, 4 May 2020 3:20 PM
To: s9(2)(a)
Cc: s9(2)(a)
Subject: Updated TPDR - Nardil (TT50-0702/1)

Dear s9(2)(a)

Thank you for your email.
As requested the product status for Nardil, Tablet, film coated 15mg (UK source) (TT50-0702/1) has been updated to "Not Available".
Attached is the updated TPDR report for your records. The changes will be reflected overnight on the Medsafe website.

Kind regards
s9(2)(a)

s9(2)(a) | Assistant Advisor | Product Regulation | Medsafe | Ministry of Health | s9(2)(a)
s9(2)(a)

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

The Ministry of Health have changed their email: Please be aware that we have change our email addresses. They now follow the following format: firstname.lastname@health.govt.nz
IMPORTANT NOTICE:
Due to the current situation with the COVID19, please do not send in hardcopy submissions until further notice.
Please visit the Medsafe website for regular updates and more information on how to register with our Electronic File Transfer system (EFT): **https://www.medsafe.govt.nz/Medicines/policy-statements/SubmittingApplicationsElectronically.asp.**

----- Forwarded by s9(2)(a) /MOH on 04/05/2020 02:45 p.m. -----

From: s9(2)(a)
To: "medsafeapplications@health.govt.nz" <medsafeapplications@health.govt.nz>,
Cc: s9(2)(a)
Date: 29/04/2020 03:25 p.m.
Subject: Product Status Change Request - Nardil (TT50-0702/1)- Consent given to Not available

Dear Medsafe applications team,

Please attached Product Status Change Request Form to change the status of Nardil (TT50-0702/1) from Consent given to Not available.

PHARMAC have been informed on the discontinuation.

If you have any questions, please do not hesitate to contact me.

Kind regards,
s9(2)(a)

s9(2)(a)
Senior Regulatory Affairs Associate
LINK
A CLINIGEN COMPANY

Link (A Clinigen Company)
t.+612 8401 9777 m.s9(2)(a)
e.s9(2)(a)
w. https://www.clinigengroup.com/global-offices/australia-new-zealand

133 Molesworth Street
PO Box 5013
Wellington 6140, New Zealand
T +64 4 496 2000

THERAPEUTIC PRODUCT DATABASE REPORT

File ref: TT50-0702/1

Trade Name	Dosage Form	Strength	Identifier
Nardil	Tablet, film coated	15 mg	(UK source)

Sponsor	Registration situation	Classification
Link Pharmaceuticals Ltd Suite 32 Level 26, PwC Tower 188 Quay Street Auckland 1010	Not available, approved: 15/12/2005	Prescription medicine

Composition

Component	Active Ingredients	Excipients
Tablet, film coated	Phenelzine sulfate 25.83mg equivalent to phenelzine 15 mg (BP)	Other excipient Magnesium stearate 6.58mg Maize starch 4.42mg Mannitol 178.83mg Opadry red 20A25096 13.28mg Povidone 6.6mg (Povidone (Grade 30))

Manufacture of Active Ingredient

Phenelzine sulfate

Siegfried Evionnaz SA
Route du Simplon 1, 36
Evionnaz 1902
SWITZERLAND

Manufacture of Final Dose Form

Recipharm Limited
Vale of Bardsley
Ashton-Under-Lyne
Lancashire OL7 9RR
UNITED KINGDOM

Haupt Pharma Wulfing GmbH
Bethelner Landstrasse 18
Gronau/Leine D-31028
GERMANY

Finished Product Testing

Haupt Pharma Wulfing GmbH
Bethelner Landstrasse 18
Gronau/Leine D-31028
GERMANY

Recipharm Limited
Vale of Bardsley
Ashton-Under-Lyne
Lancashire OL7 9RR
UNITED KINGDOM

Packing

Haupt Pharma Wulfing GmbH
Bethelner Landstrasse 18
Gronau/Leine D-31028
GERMANY

Recipharm Limited
Vale of Bardsley
Ashton-Under-Lyne
Lancashire OL7 9RR
UNITED KINGDOM

Secondary Packaging

The Uniting Church in Australia
Property Trust (NSW) for Wesley
Mission
211 Victoria Road
Dundas
NSW 2117
AUSTRALIA

NZ Site of Product Release

Link Pharmaceuticals Ltd
Suite 32
Level 26, PwC Tower
188 Quay Street
Auckland 1010

Packaging

Package	Contents	Shelf Life
Bottle, plastic HDPE with push-lock PP cap with an induction heat sealed liner	100 tablets	18 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze).
Tablet container, plastic polyethylene safety bottle	100 tablets	18 months from date of manufacture stored unopened at 2-8°C - do not freeze (opened shelf life the same)

Indications

For the treatment of major depression.
Phenelzine sulfate should rarely be the first antidepressant medicine used. Rather it is more suitable for use with patients who have failed to respond to the medicines more commonly used for these conditions

*** End of Report ***

LINK
A CLINIGEN COMPANY

PO Box 718
Mona Vale
NSW 1660
Australia

+61 2 8401 9777
+61 2 8401 9788
info@linkhealthcare.com.au

April 2020

Important Announcement: Nardil Discontinuation

NARDIL phenelzine 15mg (as sulfate) tablet bottle

Dear Valued Customer,

This notification is to inform you of the discontinuation of **NARDIL (phenelzine) tablets**.

Due to situations beyond our control, the manufacturing site for NARDIL phenelzine 15mg (as sulfate) tablet bottle has closed. Link had arranged supply of an unregistered alternative product, Canadian registered NARDIL ERFA phenelzine 15mg tablets USP, however we are now informed that this product will not be available throughout 2020.

Despite our continued attempts, Link have not been able to secure adequate alternative options to cover the anticipated phenelzine requirements throughout 2020.

Patients are advised to discuss alternative treatment options with their Doctor as soon as possible.

We thank you for your understanding during this unfortunate circumstance.

Kind regards,

Amanda Whiteman
Business Unit Manager

LHCNZ_NAR03_Mar20

FILE NOTE

From / By / Author: **Nerissa Ramlall**

Type of event: **Phone call**

Date & Time: 03/04/2020

People Involved / Present PHARMAC: **Nerissa Ramlall (NR)**

People Involved / Present: Out of Scope

- Phenelzine sulphate
  - HM noted Link are definitely sending out the discontinuation communications to the Australian market.
  - NR advised Link has an obligation to supply, cannot notify the market of a discontinuation. Have to provide written notice for PHARMAC to consider etc.
  - HM noted the original registered (Nardil) product was not going to be manufactured anymore.
  - HM advised 1 month SOH and wholesalers 1 month.
  - HM stated Link was still actively looking for alternatives, but there was no active ingredient available.
  - HM noted just under 2 months within the supply chain.

Out of Scope

FILE NOTE

From / By / Author: **Nerissa Ramlall**

Type of event: **Phone call**

Date & Time: 22/04/2020

People Involved / Present PHARMAC: **Nerissa Ramlall (NR)**

People Involved / Present: s9(2)(a)

Out of Scope

- Phenelzine sulphate
  - NR asked if any alternatives were secured. HM noted Link was unable to secure any alternatives which could guarantee continuity of supply.
  - HM advised the most it was able to find was a supplier in the USA which could only supply two units.
  - HM noted they were initially unsure if the registered Nardil was going to come back into supply, the second s29 was now out of stock and the second s29 was also out of stock. HM noted there was lots of difficulty in sourcing alternatives as there was a global supply issue.
  - NR asked if the 600 units they were previously expecting was arriving. HM advised the supplier had confirmed this order was not going to be filled.
  - NR asked if Link had exhausted options via other suppliers, noted Medsurge may have a product and could work with them.
  - HM noted and advised Australia was completely out of stock. HM noted she was aware that Medsurge had applied for s19 in Australia to ensure continuity of supply, but this was applied for prior to securing a product. HM noted she was aware the ETA was set as July, but was not sure where this product was coming from or if it was actually secured.
  - NR reiterated critical to ensure continuity. HM still to look for alternatives.
  - Discontinuation of registered Nardil product.

Out of Scope

From: Nerissa Ramlall
Sent: Friday, 8 May 2020 5:28 pm
To: s9(2)(a)
Subject: Phenelzine sulphate delisting timeframes

Hi s9(2)(a)

Thanks for your time on the phone.

In accordance with your notified discontinuation of phenelzine sulphate tab 15 mg, we will be delisting the Nardil, Nardil s29 and Lupin brands from the Pharmaceutical Schedule.

This is proposed to be from 1 October 2020, subject to an internal decision making process. This timeframe should allow for any residual claiming within the supply chain.

Accordingly, are you able to please submit an NOPC by the 12th of May .

Hope you have a nice weekend.

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | M: +64 21 960 955 www.pharmac.govt.nz

From: s9(2)(a)
Sent: Thursday, 16 April 2020 2:43 pm
To: Nerissa Ramlall s9(2)(a)
Cc: s9(2)(a) - Medsurge Healthcare s9(2)(a)
Subject: Re: Phenelzine sulphate - alternatives

Hi Nerissa,

Thank you for your email. I hope you are doing well in this unprecedented times.

I believe their is a shortage of this product in Australia as well and our supply chain Is currently working on alternative product.

I have copied this email to our operations manager. He will update you shortly.

Regards
s9(2)(a)

On 16 Apr 2020, at 11:16 am, Nerissa Ramlall s9(2)(a) wrote:

Hi s9(2)(a)

I hope this email finds you well.

I am getting in touch in regard to phenelzine sulphate tab 15 mg.

We are looking for potential alternative products, as a result of a supply issue.

Would it be possible to please look into this and advise if you have access to an appropriate product?

Many thanks and kind regards,

Nerissa

Nerissa Ramlall | Contract Manager
PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Thursday, 16 April 2020 6:31 pm
To: Nerissa Ramlall s9(2)(a)
Subject: RE: IMPORTANT: Phenelzine sulphate Stock on Hand in Wholesaler Chain

Hi Nerissa

Thank you for your email and suggested importers. We are aware of them and they are unable to supply at all to support the market.

The product we are discontinuing is the registered brand that has been unavailable for some time now as PHARMAC have been aware. It is not coming back into manufacturing and we advised as soon as we were aware. During this to support the market, we located some Section 29 supply.

We did have some alternatives supplied under Section 29 but these have been depleted and we have notified you as soon as we were aware of this. As mentioned a shipment of 600 units is now no longer available and delayed with no date of return due to manufacturing issues.

We will continue to search but would encourage you if you have alternative connections and or suppliers to look at these avenues. We are unlikely to find an alternative supply at this time due to the issue with manufacturing. Please note that this situation has also occurred in Australia and they are at or near total out of stock this month also.

Yes certainly I will keep you informed as an when information comes to hand.

Kind Regards
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)>
Sent: Thursday, 16 April 2020 3:30 PM
To: s9(2)(a)
Subject: RE: IMPORTANT: Phenelzine sulphate Stock on Hand in Wholesaler Chain

Hi s9(2)(a)

As you can imagine, there is concern around the discontinuation of phenelzine sulphate and the notice period provided. I note that we understand the difficulty involved in securing alternatives and appreciate the efforts taken so far.

Are you able to please advise if you have an update on alternatives for phenelzine sulphate?

One of my colleagues has received some information regarding potential importers which may be able to assist and they have asked for me to pass this on. This is as follows: Target, Alium, Mawdsleys, Durbin, WEP Clinical and Waymade.

Please keep me informed with how this is progressing.

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Wednesday, 15 April 2020 4:39 PM
To: Nerissa Ramlall <s9(2)(a)
Subject: RE: IMPORTANT: Phenelzine sulphate Stock on Hand in Wholesaler Chain

Hi Again Nerissa

Stock on Hand at wholesalers

58 CDC
20 Propharma
TBC PWL waiting to hear back
78 Total as per today

We would usually go through 120 per month but the last few weeks have seen an huge increase in demand and we are unlikely to find any more stock that we can guarantee in the next few weeks or months.
Note ONELINK only order when they have an order from a patient so they have no stock.
As soon as I hear what PWL have Ill advise you.

Kind Regards
s9(2)(a)

From: s9(2)(a)
Sent: Wednesday, 15 April 2020 1:35 PM
To: Nerissa Ramlall <s9(2)(a)
Subject: RE: IMPORTANT: Phenelzine sulphate 1. registered stock discontinuation letter on HOLD 2. Unlicensed options (1-2 mths SOH in NZ)

Hi Nerissa

I've answered below for convenience and accuracy.

Kind Regards
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Wednesday, 15 April 2020 1:31 PM
To: s9(2)(a)

Subject: RE: IMPORTANT: Phenelzine sulphate 1. registered stock discontinuation letter on HOLD 2. Unlicensed options (1-2 mths SOH in NZ)

Hi s9(2)(a)

Apologies for missing your call.

Are you able to please advise on the reason for the delay on the 600 units?

- Our supplier can not access this stock due to API manufacturing issues

I note that your previous email indicated that there would be sufficient stock on hand to provide cover until approximately May. Was this inclusive of the expected 600 units?

- Yes under normal circumstances but demand increased. Im waiting on wholesalers to advise what SOH they have

Please let me know once you have received the information on wholesaler stock levels.

- Yes asap

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Wednesday, 15 April 2020 12:58 PM
To: Nerissa Ramlall <s9(2)(a)
Subject: IMPORTANT: Phenelzine sulphate 1. registered stock discontinuation letter on HOLD 2. Unlicensed options (1-2 mths SOH in NZ)

Hi Nerissa

Just tried to call you with an update before emailing.

The news is not good. We were expecting 600 units of:

- 107851 Phenelzine sulphate (Lupin) 15mg tab (x60) into Auckland end of the this week, however, our supplier advised:

> *"I just received and update from our suppliers. The ETA has changed. They say this product is supposed to be restocked on **May**. However, at this point, **I can't assure you that it will be back** in stock on that date. They've been changing ETA lately."*

I suspect that the May deadline will be pushed out again also as this is the second time they have done so.

The wholesalers, we are still waiting for replies on stock and Ill advise asap that we here quantities.

We are still searching for alternatives with no success as it seems that there is an API manufacturing issue so no one can find quantities to supply markets ongoing or even for a few weeks at this stage.

We would also like to review when we send out the discontinuation letter for the registered stock (as now both options are depleted).

Kind Regards
s9(2)(a)

From: Nerissa Ramlall s9(2)(a)
Sent: Tuesday, 14 April 2020 2:39 PM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 1. registered stock discontinuation letter on HOLD 2. Unlicenced options (1-2 mths SOH in NZ)

Hi s9(2)(a)

Are you able to please provide an update on phenelzine sulphate.

In particular, information on the following would be useful:

- Updated expected stock cover for SOH and within wholesaler channels
- Update on whether any alternatives are available?

Many thanks,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Friday, 3 April 2020 12:30 PM
To: Nerissa Ramlall <s9(2)(a)
Subject: Phenelzine sulphate 1. registered stock discontinuation letter on HOLD 2. Unlicenced options (1-2 mths SOH in NZ)

Hi Nerissa

Thank you so much for the call this morning. To review and advise:

PHARMAC understand that Australia is releasing a notification of discontinuation of the registered brand Nardil to customers in Australia and TGA at 5pm this Friday, today.

For NZ, LINK will **hold the notification to MedSafe and Customers**.

There are two issues:

i. **Registered stock on contract: 100310 Nardil (phenelzine sulphate) 15mg tab (x 100).** The original registered brand that has been out of stock for some time. Out of Stock.
   1. LINK to hold MedSafe and customer notification of discontinuation until further notice

ii. **Unlicenced options supplied when registered stock depleting**: We have a little less than one month SOH and wholesaler chain has one month (but this could change quickly in the current environment). We understand that there are no alternatives, but continue to search.
   2. 107050 Nardil ERFA (phenelzine sulfate) 15mg tab (x60). Which was the Section 29 supplied stock as an alternative to the above registered stock. Out of Stock.
   3. 107851 Phenelzine sulphate (Lupin) 15mg tab (x60). It the second Section 29 product. Currently being sold.

Can we touch base moving forward and if you require more info please advise.

Kindest Regards and call any time
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Thursday, 2 April 2020 4:48 PM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 97 units SOH Important

Hi s9(2)(a)

Thanks for sending this through.

Are you able to hold off from sending out the communications regarding the discontinuation of Nardil until we have had a chance to look into it further.

I will discuss this with the relevant therapeutic group manager and be in touch tomorrow.

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Thursday, 2 April 2020 3:30 PM
To: Nerissa Ramlall <s9(2)(a)

Subject: RE: Phenelzine sulphate 97 units SOH Important
Importance: High

Hi Nerissa

I am just in the middle of a total summary of projects for you in one email.

Nardil (phenelzine) was at the top. So here is the current situation:

Phenelzine

- There have been 3 phenelzine products
  - 100310 Nardil (phenelzine sulphate) 15mg tab (x 100). The original registered brand that has been out of stock for some time. Out of Stock.
    1. Attached is a customer notification on this product which we are releasing to retail pharmacies and hospital pharmacies including wholesalers on Friday 3 at 5pm
  - 107050 Nardil ERFA (phenelzine sulfate) 15mg tab (x60). Which was the Section 29 supplied stock as an alternative to the above registered stock. Out of Stock.
  - 107851 Phenelzine sulphate (Lupin) 15mg tab (x60). It the second Section 29 product. Currently being sold.
    1. 97 units left in stock which is around one month, little less (CDC have one month also and haven't got other wholesalers at this stage)
    2. Our supplier has informed us that **no more stock is available. While we continue to search for stock we are not hopeful.**
    3. Our Australian company is also releasing this letter and notifying Clinical groups. We are also advising MedSafe on same day
  - Tablet appearance: Are you able to please confirm if the Lupin brand tablets look physically similar to the current product
    1. Our medinfo team are unable to provide this info at the moment but have asked.

We will continue to search everywhere but at this stage I have not confirmed supply other than above.

Ill keep in touch if this situation changes.

Kind Regards
s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Thursday, 2 April 2020 3:07 PM
To: s9(2)(a)
Subject: FW: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

I hope you're well.

Just following up on the questions below. Are you able to please advise?

Many thanks,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Nerissa Ramlall
Sent: Tuesday, 24 March 2020 11:56 AM
To: s9(2)(a)
Subject: RE: Phenelzine sulphate 120 units SOH

Hi s9(2)(a)

Thanks for your email.

Were you able to advise on what the stock levels are at the wholesale level, do you anticipate that this is around one months' worth of stock?

I've also received a question from the therapeutic group manager regarding the Lupin alternative. Are you able to please confirm if the Lupin brand tablets look physically similar to the current product?

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: s9(2)(a)
Sent: Tuesday, 24 March 2020 11:18 AM
To: Nerissa Ramlall <s9(2)(a)
Subject: Phenelzine sulphate 120 units SOH

Dear Nerissa

I will put this onto your weekly SOH update so that you can see the situation.
We still have 120 units SOH as per last week as no new purchase orders from wholesalers. I expect this to change this week.

Ill update you shortly.

s9(2)(a)

From: Nerissa Ramlall <s9(2)(a)
Sent: Friday, 20 March 2020 11:31 AM
To: s9(2)(a)
Subject: Phenelzine sulphate Out of Scope

Hi s9(2)(a)

Thanks for your time on the phone yesterday.

Are you able to please look into the stock levels at wholesaler level and advise what these are? This would be useful for me to get a better understanding of the supply chain impact.

Out of Scope

Kind regards,

Nerissa

Nerissa Ramlall | Contract Manager
PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
s9(2)(a) | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz