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21 July 2023

Dear Pharmacist,

Lamictal (lamotrigine) tablet packaging change

GlaxoSmithKline (GSK) would like to advise that Lamictal (lamotrigine) 25mg, 50mg, 100mg chewable/dispersible tablets will undergo a packaging change to a new child-resistant safety foil packaging.

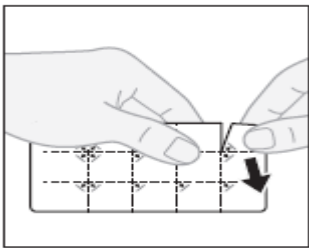
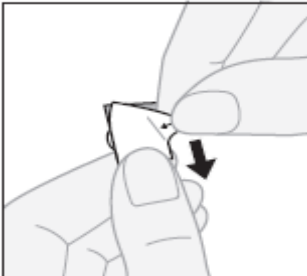
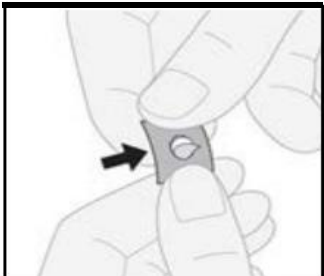
There are no changes being made to the formulation of Lamictal (lamotrigine) 25mg, 50mg and 100mg chewable/dispersible tablets. Lamictal 2mg and 5mg, which are in bottle packaging, are not affected.

It is GSK policy in line with applicable regulations to ensure that children are protected from the serious risk of adverse events from accidental drug exposure. GSK has assessed its portfolio of product packaging and is implementing child resistant packaging where a risk to children is identified.

The new child-resistant safety foil packaging for Lamictal (lamotrigine) is intended to prevent unwanted opening by children and reduce the risk of accidental adverse events from a child gaining unwanted access to medicines.

For Lamictal (lamotrigine) chewable/dispersible tablets, GSK determined that the child-resistant safety foil peel push option is the best way to satisfy the many user requirements of our packaging.

Instructions on how to open the new child-resistant safety foil packaging can be found within the Lamictal (lamotrigine) Consumer Medicines Information on the Medsafe website and a summary provided below:

<p>1. Separate one tablet: tear along the cutting lines to separate one "pocket" from the blister.</p>	<p>2. Peel back the outer layer: starting at the corner, lift and peel over the pocket.</p>	<p>3. Push out the tablet: gently push one end of the tablet through the foil layer.</p>
		

To support patients on Lamictal (lamotrigine) and healthcare professionals with this change, GSK has made resources available to enable effective communication on how to open the new child-resistant safety foil packaging.

A patient instructional leaflet and video are available and can be utilised to support patients on Lamictal (lamotrigine) with opening the new child-resistant safety foil peel push packaging.

The digital version of the patient instructional leaflet can be found attached to this email. Printed copies can be requested by emailing; gskorders@medidata.co.nz or please reach out to GSK medical information (mel.australia-medinfo@gsk.com) for digital or printed patient instructional leaflets.

The instructional video can be found by scanning the QR code below:



For your awareness, the new child-resistant safety foil peel push packaging will have the following estimated dates of supply within pharmacies (which may be subject to change):

Product	Pharmacode	Current packaging	New packaging	Estimated first supply to pharmacies
Lamictal 25mg x 56 tablet	417866	Blister pack	Child-resistant safety foil	Early September
Lamictal 50mg x 56 tablet	418021			Late-July
Lamictal 100mg x 56 tablet	418498			Mid-August

GSK asks for your support in advising and counselling patients about the new child-resistant safety foil packaging when it is dispensed and to provide assurance that there has been no changes made to the formulation of Lamictal (lamotrigine) 25mg, 50mg and 100mg chewable/dispersible tablets.

GSK would like to thank you for your support to patients through this change. For further queries regarding Lamictal (lamotrigine), please contact GSK Medical Information at 0800 800 500 or mel.australia-medinfo@gsk.com.

Yours sincerely,



Kate McLaren
Medical Operations Manager
GlaxoSmithKline NZ Limited

Lamictal (lamotrigine) tablets contain 2mg, 5mg, 25mg, 50mg or 100mg of lamotrigine. Lamotrigine is a use-dependent blocker of voltage-gated sodium channels. It produces a use- and voltage-dependent block of sustained repetitive firing in cultured neurones and inhibits pathological release of glutamate (the amino acid which plays a key role in the generation of epileptic seizures), as well as inhibiting glutamate-evoked bursts of action potentials.

Lamictal is indicated in adults, adolescents and children for adjunctive therapy in the treatment of epilepsy, for partial and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome and in adults for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.

Lamictal is a **prescription medicine**. Before prescribing *Lamictal*, please review the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is available at www.medsafe.govt.nz. Trademarks are owned by or licensed to the GSK group of companies.

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GlaxoSmithKline NZ Limited, Auckland. **Adverse events involving GSK products should be reported to GSK Medical Information on 0800 808 500.** GlaxoSmithKline NZ Limited, Auckland. TAPS DA2301VL; PM-NZ-LMT-LTR-230001. Date of Approval: **Jul 2023** Date of Expiry: **Jul 2024**