

14 July 2014

Decision to fund rifaximin (Xifaxan) for hepatic encephalopathy

PHARMAC is pleased to announce the decision to award the tender to Norgine for Sole Subsidised Supply Status and Hospital Supply Status for rifaximin (Xifaxan) that was included in the 2013/2014 Invitation to Tender, dated 07 November 2013. In summary, the effect of the decision is that:

- rifaximin will be funded for the treatment of hepatic encephalopathy from 1 August 2014 (see also the 30 June 2014 Tender Notification (<http://www.pharmac.health.nz/news/notification-2014-06-30-tender/>); and
- rifaximin funding will be subject to Special Authority criteria in the community and restrictions in DHB hospitals.

A proposal to list rifaximin with Special Authority criteria was subject of a consultation letter dated 14 January 2013, which can be found on PHARMAC's website at <http://www.pharmac.govt.nz/2013/01/14/Link%20Pharmaceuticals%20Consultation.pdf>.

That proposal was to list an unapproved brand of rifaximin and PHARMAC was made aware during consultation that an approved rifaximin product may soon become available, so the proposal was not progressed (refer to notification dated 7 March 2013 (<http://www.pharmac.health.nz/assets/notification-2013-03-07-funding-unapproved-medicines.pdf>)).

Details of the decision

- Rifaximin (Xifaxan) tablets will be listed in Section B, and in the Hospital Medicines List (HML, Part II of Section H), of the Pharmaceutical Schedule from 1 August 2014 at a price and subsidy of \$625.00 per 56 tablets (ex-manufacturer, excluding GST).

| Chemical | Presentation | Brand | Pack size | Price and subsidy |
|-----------|--------------|----------------------|-----------|-------------------|
| Rifaximin | Tab 550 mg | Xifaxan (Norgine) | 56 | \$625.00 |

- Rifaximin (Xifaxan tablets) will be listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria:

Initial application only from a gastroenterologist or hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist.

Approvals valid for six months where the patient has hepatic encephalopathy despite an adequate trial of maximum tolerated doses of lactulose.

Renewal only from a gastroenterologist or hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist.

Approvals valid without further renewal where the treatment remains appropriate and the patient is benefiting from treatment.

- Rifaximin (Xifaxan) tablets will be listed in the HML subject to the following restriction:

Restricted

For patients with hepatic encephalopathy despite an adequate trial of maximum tolerated doses of lactulose.

- The Special Authority criteria were amended from those initially consulted on following discussions with relevant specialists. The requirement of two previous episodes of hepatic encephalopathy has been removed and changes made to allow prescribers to initiate treatment on the recommendation of a gastroenterologist or hepatologist.

Changes for existing patients on rifaximin

PHARMAC notes that prior to the availability of the Medsafe approved rifaximin (Xifaxan 550 mg tablets), an unapproved product (Normix 200 mg tablet) was frequently used to treat hepatic encephalopathy and this required a different dosing regimen of 600mg twice daily or 400mg three times a day. PHARMAC would like to highlight the difference in strengths and dosing regimen between these two (approved and unapproved) products.

Patients who currently receive funded rifaximin approved via the EC/NPPA mechanism may need to change brands to Xifaxan 550 mg tablets in order to continue to receive fully funded rifaximin for hepatic encephalopathy. This will involve a dose change and require a new prescription from their clinician. PHARMAC will be contacting clinicians and pharmacists involved in the care of all existing patients on funded rifaximin to explain the process for changing the brand and dose.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

| Theme | Comment |
|---|--|
| Support the proposal and agree with the proposed Special Authority criteria. | PHARMAC notes the amended Special Authority criteria (from those initially consulted on) slightly widen access to rifaximin to patients who are considered clinically appropriate by prescribing clinicians. |
| Request to consider funding rifaximin for patients with small bowel bacterial overgrowth in short bowel syndrome and/or intestinal failure. | PHARMAC considers this indication would require assessment as a separate funding application. |

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.