

11 July 2008

## Funding of levetiracetam approved

PHARMAC's Board has approved the funding of the Keppra brand of the antiepilepsy agent levetiracetam for selected patients via a special access process, from 1 August 2008.

The Board also approved funding of Rex Medical Ltd's brand of levetiracetam (Levetiracetam-Rex) for all patients as soon as possible following Medsafe registration. The listing of Levetiracetam-Rex is unlikely to occur prior to mid-2010.

We appreciate all the feedback we received and acknowledge the time people took to respond. All consultation responses were considered in their entirety when making a decision on the proposal.

## What the decisions will mean

From 1 August 2008 clinicians will be able to apply for Levetiracetam Special Access (LSA) funding for patients who have tried and failed on, or are unable to take, currently funded antiepilepsy agents.

LSA application forms will be available from 1 August 2008 on PHARMAC's website: [www.pharmac.govt.nz](http://www.pharmac.govt.nz) or from the LSA coordinator: (04) 916-7553 or [lsacoordinator@pharmac.govt.nz](mailto:lsacoordinator@pharmac.govt.nz).

Applications will be considered by a panel of clinicians (the LSA Panel) at the soonest practicable opportunity following receipt of the application. Following a recommendation from the LSA Panel, a decision on LSA funding for each patient will be made and the decision will be notified to the applying clinician.

From the date of listing of Levetiracetam-Rex in the Pharmaceutical Schedule all patients would have access to subsidised levetiracetam without Special Authority restrictions.

## More information on following pages

More details about the decisions can be found on the following pages. If you have any queries about these changes, you can call our toll free number (9 am to 5 pm) on 0800 66 00 50.

## Details of the decisions

### *Levetiracetam Special Access*

From 1 August 2008 until a fully funded registered version of levetiracetam is listed in the Pharmaceutical Schedule, levetiracetam will be available to selected patients via application to the newly formed Levetiracetam Special Access (LSA) Panel. Applications will be considered by the LSA Panel at regular meetings and a recommendation for funding will be made subject to compliance with the eligibility criteria.

Applications will be considered for patients meeting the following criteria:

1. Patient has been diagnosed with epilepsy; and
2. All currently subsidised antiepilepsy agents have been given a reasonable trial\* or are contraindicated or unsuitable (details of treatment to be provided by applicant); and
3. Either:
  - 3.1 seizures are not adequately controlled with currently subsidised antiepilepsy agents; or
  - 3.2 seizures are controlled adequately but the patient has experienced unacceptable side effects from currently funded antiepilepsy agents;and
4. Details of the patient's treatment history are attached, including details of subsidised pharmaceuticals that have been trialed or considered.

\*A reasonable trial is defined as treatment with subsidised antiepilepsy agents, given alone or in combination, which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

Applications will need to be made on the approved LSA forms, which will be available from 1 August 2008 on PHARMAC's website: [www.pharmac.govt.nz](http://www.pharmac.govt.nz) or from the LSA coordinator: (04) 916-7553 or [lsacoordinator@pharmac.govt.nz](mailto:lsacoordinator@pharmac.govt.nz).

Completed application forms will need to be sent to the LSA coordinator and will be considered by the LSA Panel at the next practical opportunity following receipt of the application. Notification of the decision would then be sent to the applying clinician.

Initial approvals will be valid for 6 months, with renewals of 12 months where the applicant has demonstrated a clinical need for continued treatment with levetiracetam.

LSA funding will be approved for the Keppra brand of levetiracetam only. PHARMAC has not entered into a listing contract with the supplier of Keppra. Therefore, for approved applications there is no surety of source of, or ongoing supply of, Keppra.

Approved applications will remain valid until expiry or until such time as an agreed ongoing supply of levetiracetam is available through the Pharmaceutical Schedule. After that time, neither new approvals nor renewals will be given. In order to continue to receive subsidised levetiracetam patients with existing approvals would need to use a Pharmaceutical Schedule listed brand. Any applicant who considered that their

patient should remain on the Keppra brand (if not listed in the Schedule) would need to apply in writing outlining the reasons why (at a minimum, patients must have been seizure free for at least 6 months for ongoing Keppra subsidy to be considered).

#### *Levetiracetam-Rex*

Rex Medical Ltd's brand of levetiracetam (Levetiracetam-Rex) will be listed in Sections B and H of the Pharmaceutical Schedule as soon as possible following Medsafe registration at the following prices and subsidies (ex-manufacturer, excluding GST):

<b>Pharmaceutical</b>	<b>Brand</b>	<b>Form and Strength</b>	<b>Pack Size</b>	<b>Price and subsidy</b>
Levetiracetam	Levetiracetam-Rex	Tablet 250 mg	60	\$24.03
Levetiracetam	Levetiracetam-Rex	Tablet 500 mg	60	\$28.71
Levetiracetam	Levetiracetam-Rex	Tablet 750 mg	60	\$45.23

Subject to Medsafe approval, Levetiracetam-Rex will be funded without the requirement for Special Authority approval, meaning that it would be subsidised if prescribed by any relevant practitioner for any patient.

Levetiracetam-Rex will have protection from delisting and subsidy reduction for a period of 3 years after the date of listing or until 1 July 2013, whichever is sooner.