

29 May 2009

## Proposal to list Clarithromycin 500 mg tablets

PHARMAC is seeking feedback on a proposal to fund clarithromycin 500 mg tablets (Klamycin) on the Pharmaceutical Schedule.

In summary, this proposal would result in:

- Klamycin 500 mg tablets being listed in Section B of the Pharmaceutical Schedule under an endorsement restriction from 1 October 2009;
- Klamycin 500 mg would have subsidy and delisting protection until 30 June 2011; and
- the Special Authority for helicobacter pylori infections that applies to clarithromycin 250 mg tablets would be removed.

Further details of the proposal can be found below and on the following page.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Wednesday, 11 June 2009** to:

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Therapeutic Group Manager  
PHARMAC

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

### Details of the proposal

- PHARMAC and Mylan New Zealand Limited have entered into a provisional agreement relating to the supply of clarithromycin 500 mg tablets (Klamycin).
- Klamycin 500 mg tablets would be listed in the Alimentary Tract and Metabolism therapeutic group (Helicobacter Pylori Eradication) of Section B of the Pharmaceutical Schedule from 1 October 2009 at the following prices and subsidies (ex-manufacturer and exclusive of GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Clarithromycin	500 mg tablet	Klamycin	14	\$23.30

- Clarithromycin 500 mg tablets would be funded with the following endorsement:

**Only if prescribed for the eradication of Helicobacter pylori infections and the prescription is endorsed accordingly**

**Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole.**

- PHARMAC proposes to amend the Special Authority for clarithromycin 250 mg tablets as follows (deletions in strikethrough):

Special Authority for Subsidy - Form SA0657

~~Initial application - (Helicobacter pylori infections) only from a general practitioner or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:~~

~~Both:~~

- ~~1 Eradication of Helicobacter pylori in patient with proven infection; and  
2 Peptic ulcer disease proven by endoscopy.~~

~~Note~~

~~Maximum of two prescriptions (two courses) per patient.~~

**Initial application** - (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 Mycobacterium Avium Intracellulare Complex infections in patient with AIDS; or
- 2 Atypical and drug-resistant mycobacterial infection; or
- 3 All of the following:
  - 3.1 Prophylaxis against disseminated Mycobacterium Avium Intracellulare Complex infection; and
  - 3.2 HIV infection; and
  - 3.3 CD4 count  $\leq$  50 cells/mm<sup>3</sup>.

**Renewal** - (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

## Background

PHARMAC currently funds clarithromycin 250 mg tablets, at a maximum of 500 mg per prescription, or in a combination pack with omeprazole and amoxicillin (Losec Hp7 OAC). The current 500 mg maximum per prescription of clarithromycin can be waived for helicobacter pylori eradication and for Mycobacterial infections under a Special Authority.

Under the proposal clarithromycin 500 mg tablets would be fully funded when prescribed for helicobacter pylori eradication, with no maximum per prescription. The proposed listing of Klamycin 500 mg under endorsement would allow treatment to be prescribed without the need for a Special Authority application, allow the prescribing of metronidazole instead of amoxicillin for people who are allergic to amoxicillin and allow the use of any fully funded proton pump inhibitors.

We note that stocks of Losec Hp7 OAC packs, as supplied by AstraZeneca New Zealand Ltd, are expected to be depleted at the end of September 2009. Thereafter, Losec Hp7 OAC packs would be discontinued and subsequently delisted from the Pharmaceutical Schedule.

For the avoidance of doubt, the current 500 mg maximum per prescription for clarithromycin 250 mg tablets would remain for Mycobacterial infections (with waiver possible via Special Authority).