

3 September 2009

## **Approval of proposal for alendronate, aprepitant, raltegravir, levodopa with carbidopa, timolol and dorzolamide with timolol**

PHARMAC is pleased to announce the approval of an agreement with Merck Sharp & Dohme (New Zealand) Limited (MSD) for the above products. This was the subject of a consultation letter dated 30 July 2009.

Key aspects of the decision are outlined below (all to be implemented 1 October 2009 unless otherwise stated); further details of the proposal can be found on the following pages.

### *Alendronate sodium, with and without cholecalciferol (Fosamax and Fosamax Plus)*

- A new strength of Fosamax Plus tablets (alendronate sodium 70 mg with cholecalciferol 5600 iu) will be funded, subject to Special Authority criteria, and the existing funded strength of Fosamax Plus will be discontinued by MSD and delisted.
- The Special Authority criteria for "Alendronate for Osteoporosis" will be amended.

### *Aprepitant (Emend)*

- Emend will be funded subject to Special Authority criteria.

### *Raltegravir (Isentress)*

- Isentress will be funded subject to Special Authority criteria.

### *Levodopa with carbidopa (Sinemet and Sinemet CR)*

- The price and subsidy for Sinemet and Sinemet CR will be reduced.
- The "Specialist" restriction will be removed from Sinemet CR.

### *Timolol maleate and dorzolamide hydrochloride with timolol maleate (Timoptol XE and Cosopt)*

- The price and subsidy for Cosopt will be reduced; there will be no changes to the listing of Timoptol XE.

### *Patent litigation*

- Patent revocation proceedings initiated by PHARMAC in the High Court, and associated court action commenced by Merck & Co, Inc (Merck) and MSD, in relation to Merck's patent NZ501807 will be discontinued.
- Patent NZ501807 relates to the use of alendronate for the manufacture of a medicament for inhibiting bone resorption where the medicament is in a unit dosage form which comprises about 70 mg and has a dosing interval of once weekly, and expires on 17 July 2018.

## Details of the decision

### Alendronate sodium with and without cholecalciferol (Fosamax and Fosamax Plus)

Fosamax and Fosamax Plus will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at the following prices and subsidies (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Price and subsidy from 1 Oct 2009	Price and subsidy from 1 May 2011	Price and subsidy from 1 July 2014
Alendronate sodium	Fosamax	Tab 70 mg	4	\$35.91*	\$22.90	\$12.90
Alendronate sodium with cholecalciferol	Fosamax Plus	Alendronate tab 70 mg with cholecalciferol 2800 iu	4	\$35.91*	Delisted	Delisted
Alendronate sodium with cholecalciferol	Fosamax Plus	Alendronate tab 70 mg with cholecalciferol 5600 iu	4	\$35.91	\$22.90	\$12.90

\* no change in price or subsidy from the current listed price and subsidy.

MSD will discontinue supply of the existing funded strength of Fosamax Plus (alendronate sodium 70 mg with cholecalciferol 2800 iu tablets) from approximately October 2009 and PHARMAC will delist it from the Pharmaceutical Schedule approximately 6 months later.

A confidential rebate will apply to community subsidies and hospital dispensings of Fosamax and both strengths of Fosamax Plus.

Fosamax and the higher strength of Fosamax Plus (alendronate sodium 70 mg with cholecalciferol 5600 iu tablets) will have protection from delisting and subsidy reduction until 1 August 2018.

Fosamax and Fosamax Plus will be subject to the current Special Authority restrictions, except that a new criterion will be added to the "Alendronate for Osteoporosis" Special Authority initial application for "Underlying cause – Osteoporosis" and renewal application for "Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause – osteoporosis' criteria" as follows (additions in bold):

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mass density (BMD)  $\geq 2.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -2.5$ ); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision will apply to many patients under 75 years of age; or

- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score  $\leq$  -3.0; or
- 5 **A 10-year risk of hip fracture  $\geq$  3%, calculated using a published risk assessment algorithm (e.g. FRAX or Dubbo) which incorporates BMD measurements.**

The listing of alendronate sodium 40 mg tablets (Fosamax) in Section B of the Pharmaceutical Schedule will remain unchanged. Alendronate sodium 40 mg tablets (Fosamax) will also be listed in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at a price of \$133.00 per 30 tablets.

Aprepitant (Emend Tri-pack)

Emend Tri-pack will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at a price and subsidy of \$116.00 (OP) per pack (two 80 mg capsules and one 125 mg capsule) (ex-manufacturer, excluding GST).

Aprepitant in Section B of the Pharmaceutical Schedule will be subject to the following Special Authority restrictions:

Initial application from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

Emend Tri-pack will have protection from delisting and subsidy reduction until 1 July 2014.

Raltegravir (Isentress)

Isentress tablets will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 as follows (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Price and subsidy from 1 October 2009	Price and subsidy from 1 January 2011
Raltegravir potassium	Isentress	Tab 400 mg	60	\$1,350.00	\$1,090.00

A rebate will apply to community subsidies and hospital dispensings of Isentress.

Raltegravir potassium listed in Section B of the Pharmaceutical Schedule will be subject to the same Special Authority restrictions that apply to the funded Antiretrovirals (Non-nucleosides Reverse Transcriptase Inhibitors, Nucleosides Reverse Transcriptase Inhibitors and Protease Inhibitors) at 1 October 2009.

Isentress will have protection from delisting and subsidy reduction until 1 July 2014.

Levodopa with carbidopa (Sinemet and Sinemet CR)

From 1 October 2009 Sinemet and Sinemet CR will be listed in Part II of Section H of the Pharmaceutical Schedule, and the prices and subsidies of two strengths of Sinemet and Sinemet CR will change in Section B of the Pharmaceutical Schedule, as follows (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Current price and subsidy	New price and subsidy
Levodopa with carbidopa	Sinemet	Levodopa tablet 100 mg with carbidopa 25 mg	100	\$20.00	\$20.00
Levodopa with carbidopa	Sinemet	Levodopa tablet 250 mg with carbidopa 25 mg	100	\$57.50	\$40.00
Levodopa with carbidopa	Sinemet CR	Levodopa long-acting tablet 200 mg with carbidopa 50 mg	100	\$70.00	\$47.50

The "Retail pharmacy-Specialist" restriction will be removed from the listing of levodopa long-acting tablet 200 mg with carbidopa 50 mg (Sinemet CR) in Section B of the Pharmaceutical Schedule from 1 October 2009.

Sinemet and Sinemet CR will have protection from delisting and subsidy reduction until 1 July 2012.

Dorzolamide hydrochloride with timolol maleate (Cosopt)

The price and subsidy for dorzolamide hydrochloride eye drops 2% with timolol maleate 0.5% (Cosopt) will reduce from \$18.50 to \$15.50 per 5 ml OP in Section B of the Pharmaceutical Schedule from 1 October 2009 (ex-manufacturer, excluding GST).

Dorzolamide hydrochloride eye drops 2% with timolol maleate 0.5% (Cosopt) will be listed in Part II of Section H of the Pharmaceutical Schedule at a price of \$15.50 per 5 ml from 1 October 2009 (ex-manufacturer, excluding GST).

A confidential rebate will apply to community subsidies and hospital dispensings of Cosopt from 1 January 2012.

Cosopt will have protection from delisting and subsidy reduction until 1 January 2014.

### Timolol maleate (Timoptol XE)

Timolol maleate eye drops (Timoptol XE) will be listed in Part II of Section H of the Pharmaceutical Schedule from 1 October 2009 at the following prices (ex-manufacturer, excluding GST):

Product	Brand	Form and Strength	Pack Size	Price
Timolol maleate	Timoptol XE	Eye drops 0.25%, gel forming	2.5 ml	\$3.30
Timolol maleate	Timoptol XE	Eye drops 0.5%, gel forming	2.5 ml	\$3.78

Both strengths of Timoptol XE will continue to be listed in Section B of the Pharmaceutical Schedule from 1 October 2009 at the above prices and subsidies (ex-manufacturer, excluding GST).

Timoptol XE will have protection from delisting and subsidy reduction until 1 January 2014.

### **Feedback received**

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 20 August 2009 were considered by the Board in their entirety prior to it making a decision on the proposed changes. Most responses were supportive of the proposal. Key issues raised in relation to specific aspects of the proposal, and our responses, are outlined below:

Theme	Comment
Some consultation responders were concerned that the additional criterion "A 10-year risk of hip fracture $\geq$ 3%" proposed for the "Alendronate with Osteoporosis" Special Authority was too loosely defined and, as a consequence, would be associated with clinical risk and financial risk from inappropriate application of the criterion.	We took additional advice from the Osteoporosis Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) about this. The wording of the additional criterion was altered as a result of the Subcommittee's advice.
Some consultation responders were concerned about inappropriate prescribing of aprepitant if it was funded subject to the proposed restrictions.	We consider that it is the responsibility of the prescriber, not PHARMAC, to determine whether or not the use of aprepitant in their patients is safe and appropriate.
Several consultation responders noted that PTAC had recommended listing darunavir at the same time as raltegravir.	We note that the two medications are supplied by different pharmaceutical companies and, given the differing state of negotiations, it was not feasible for these listings to occur at the same time. We remain open to continuing discussions with the supplier of darunavir for a listing on the Pharmaceutical Schedule.

### **More information**

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.