

30 September 2008

Proposed changes to the diltiazem hydrochloride presentations listed on the Pharmaceutical Schedule

Proposal Summary

We are proposing the following changes to the diltiazem hydrochloride presentations listed on the Pharmaceutical Schedule. The proposed changes are as a result of safety concerns regarding the prescribing and dispensing of diltiazem (not the quality of the pharmaceuticals), clinical advice regarding what presentations would be appropriate, and a competitive process for supply of diltiazem.

*The following preparations would be **delisted** from 1 June 2009:*

- Dilzem SR 90 mg and 120 mg (twice daily) sustained release capsules
- Dilzem LA 180 mg and 240 mg (once-daily) long-acting tablets

*The following preparations would **remain listed**:*

- Dilzem 30 mg and 60 mg immediate release tablets
- Cardizem CD 120 mg, 180 mg and 240 mg (once-daily) long-acting capsules

This proposal would result in the subsidisation of only Dilzem immediate release tablets and Cardizem CD once daily long-acting capsules. These products would also have Community and Hospital Sole Supply Status (this means that only Dilzem immediate release tablets and Cardizem CD once daily long-acting capsules would be available for community and hospital patients).

We would provide advice to assist clinicians and pharmacists when switching patients.

Further details of the proposal can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter writing by 4 pm on **Friday 17th of October 2008** to:

Stephen Woodruffe
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: stephen.woodruffe@pharmac.govt.nz
Fax: (04) 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board prior to making a decision on this proposal.

The Proposal

From 1 June 2009, the following diltiazem preparations would be delisted from the Pharmaceutical Schedule (until then they would remain fully funded):

Brandname	Strength	Form	Presentation	Dosing frequency
Dilzem SR	90 mg	Capsule	Sustained release	Twice daily
Dilzem SR	120 mg	Capsule	Sustained release	Twice daily
Dilzem LA	180 mg	Tablet	Long-acting	Once daily
Dilzem LA	240 mg	Tablet	Long-acting	Once daily

The following diltiazem preparations would remain listed on the Pharmaceutical Schedule:

Brandname	Strength	Form	Presentation	Dosing frequency
Dilzem	30 mg	Tablet	Immediate release	3 - 4 times daily
Dilzem	60 mg	Tablet	Immediate release	3 - 4 times daily
Cardizem CD	120 mg	Capsule	Long-acting	Once daily
Cardizem CD	180 mg	Capsule	Long-acting	Once daily
Cardizem CD	240 mg	Capsule	Long-acting	Once daily

As a result of agreements with Douglas Pharmaceuticals Limited and Sanofi-Aventis New Zealand Limited, the prices and subsidies (ex-manufacturer, exclusive of GST) of the diltiazem preparations that would remain listed in Section B and in Part II of Section H of the Pharmaceutical Schedule, would alter as follows:

Brandname	Strength and Form	Pack Size	Current price and Subsidy	Price and Subsidy from 1 December 2008	Price and Subsidy from 1 June 2009
Dilzem	30 mg tab	100	\$4.50	\$4.60	\$4.60
Dilzem	60 mg tab	100	\$8.50	\$8.50	\$8.50
Cardizem CD	120 mg cap	30	\$5.10	\$4.72	\$4.34
Cardizem CD	180 mg cap	30	\$7.65	\$7.08	\$6.50
Cardizem CD	240 mg cap	30	\$10.20	\$9.44	\$8.67

Both the Dilzem and Cardizem CD brands of diltiazem would have Community and Hospital Sole Supply Status from 1 June 2009 until 31 December 2011.

Clinical Implications

This proposal would result in the subsidisation of only Dilzem immediate release tablets and Cardizem CD once daily long-acting capsules. As these products would also have Community and Hospital Sole Supply Status they would be the only available preparations in the community and hospital setting.

Patients using Dilzem SR 90 mg and 120 mg (twice daily) sustained release capsules and Dilzem LA 180 mg and 240 mg (once-daily) long-acting tablets would be required to switch to another presentation. The alternatives for these patients would be Cardizem CD 120 mg, 180 mg and 240 mg (once-daily) long-acting capsules.

We are aware that there are a number of patients who are taking Dilzem SR 90 mg or 120 mg once daily instead of twice daily (even though this is not the recommended dosing regimen). The alternatives for these patients would be Cardizem CD 120 mg (once-daily) long-acting capsules or immediate release tablets. We note that the dose profile for these patients would change and as a result they may experience a change in effect. Additional monitoring of these patients would therefore be required.

We would provide advice to assist clinicians and pharmacists when switching patients, this would include:

- The alternatives for patients who are receiving a presentation that would be delisted.
- What to be aware of when switching patients.

Background Information

We are aware of concerns from the DHBNZ Safety and Quality of Medicines Group, regarding the occurrence of prescribing and dispensing errors as a result of confusion between the currently listed presentations of diltiazem hydrochloride.

In order to gain a greater understanding of these concerns and to determine possible options we issued a request for information which sought advice on the preferred preparations of diltiazem. A number of responses were received, many of which acknowledged that the current number of brands and formulations available are confusing and have resulted in a number of errors in their administration and prescribing. Overall, the responses supported a reduction in the available presentations, although they did differ regarding what presentations should be available.

All of the responses were reviewed by the Cardiovascular Sub-Committee of PTAC (the Pharmacology and Therapeutic Advice Committee). The Sub-Committee recommended that the twice daily preparations should be removed from the Pharmaceutical Schedule and that only one brand of the long-acting preparations should be available.

On 28 February 2008, we issued a letter indicating that there may be a number of changes to the listings of diltiazem in the Pharmaceutical Schedule as a result of safety concerns (not related to the quality of the pharmaceuticals but rather their prescribing and dispensing) and that we would provide details of the changes as they became available. In this letter we indicated that the changes may include the delisting of Dilzem SR 90 mg and 120 mg (twice daily) preparations, and the delisting of either the long-acting tablets or the long-acting capsules (but not both).

Following the letter we issued a request for proposals for the supply of immediate-release and long-acting preparations. This proposal is the result of this process.