3rd September 2014

«TITLE» «INITIALS» «SURNAME»
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Subject: **Direct Healthcare Professional Communication**

IMPORTANT SAFETY UPDATE OF PRESCRIBING INFORMATION FOR DILATREND® (carvedilol)

«TITLE» «SURNAME»

Roche Products (New Zealand) Limited ("Roche") would like to inform you about important new safety information for Dilatrend regarding severe cutaneous adverse reactions (SCAR), which has resulted in updates to the Warnings and Precautions and the Post-Marketing Undesirable Effects sections of the Dilatrend company core data sheet (CDS) and the local Data Sheet for Dilatrend.

Summary

- Very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with Dilatrend.
- Dilatrend should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to Dilatrend.

Further Information

During 24 years of post-marketing surveillance (cumulative exposure over 32 million patients), very rare cases of severe cutaneous adverse reactions have been reported with Dilatrend to the company safety database. The analysis of these cases identified one literature case with a fatal event of TEN probably causally related to treatment with Dilatrend, and a second case reporting SJS possibly causally related to treatment with Dilatrend.

As a consequence, the Warnings and Precautions and the Post-Marketing Undesirable Effects section of the Dilatrend company core data sheet (CDS) and of the local Data Sheet have been updated with this important new safety information.

New safety information added to the 'Warnings and Precautions' section

Severe cutaneous adverse reactions (SCARs): very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS) have been reported during treatment with Dilatrend. Dilatrend should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to Dilatrend.

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New safety information added to the 'Undesirable Effects – Post-Marketing Experience' section

Skin and subcutaneous tissue disorders: severe cutaneous adverse reactions (toxic epidermal necrolysis, Stevens-Johnson Syndrome) (see Warning and Precautions section).

Before prescribing, please review the full Dilatrend Data Sheet available at www.medsafe.govt.nz.

If you have any questions or require additional information regarding the use of Dilatrend, please contact Roche Medical Information by phone on 0800 276 243 or by email at auckland.medinfonz@roche.com.

Reporting Adverse Events

Roche will continue to monitor the safety of Dilatrend through established reporting mechanisms Please report any suspected adverse events via email to Roche Drug Safety at nz.drugsafety@roche.com, and to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by phone (03) 479 7247, fax (03) 479 7150 or email at carmnz@otago.ac.nz.

Yours sincerely,

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