

5 February, 2021

Dear Healthcare Professional,

Supply of Canadian-labelled COVERSYL 2 mg and 4 mg perindopril erbumine tablets in New Zealand

Following the discontinuation of supply of APO-PERINDOPRIL products in New Zealand, Servier Laboratories (New Zealand) Ltd has been requested by PHARMAC to supply Servier perindopril erbumine products as a replacement to meet an urgent shortage in the market.

Canadian-labelled COVERSYL 2 mg perindopril erbumine TT50-10867 and COVERSYL 4 mg perindopril erbumine TT50-10867a products have been granted Provisional Consent under section 23 of the Medicines Act 1981 for two years, for use in New Zealand until supply of New Zealand-labelled COVERSYL product is available.

Medsafe has determined that Canadian COVERSYL 2 mg and 4 mg is a suitable replacement for APO-PERINDOPRIL 2 mg and 4 mg, when prescribed at the same tablet strength.

The below table contains a description of the previously supplied APO-Perindopril tablets and the new Canadian-labelled COVERSYL tablets. This may be helpful for your patients to know when you are prescribing COVERSYL.

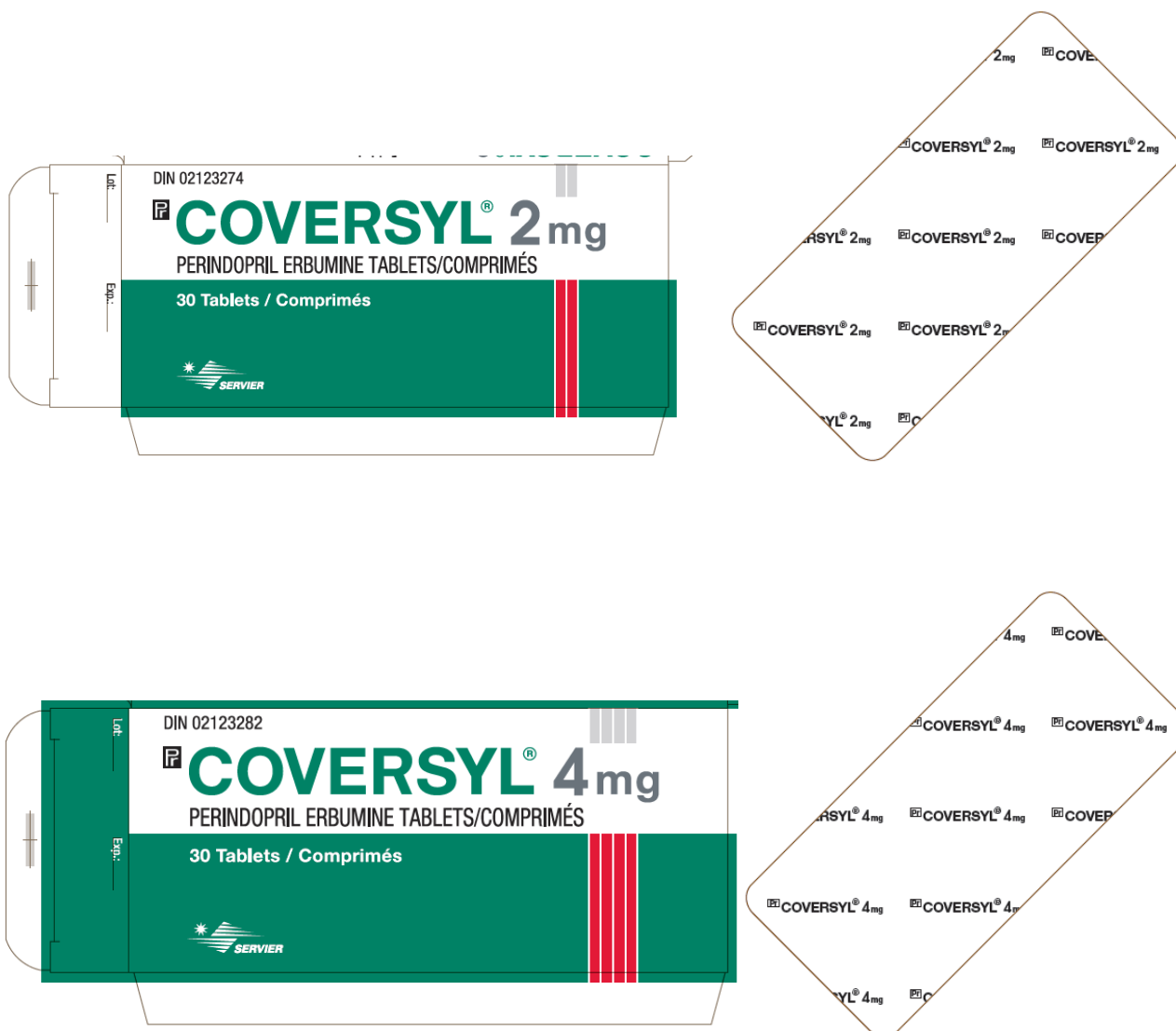
APO-PERINDOPRIL 2 mg White, round, biconvex tablets.	Canadian-labelled COVERSYL 2 mg White, round, biconvex tablets.
APO-PERINDOPRIL 4 mg White, capsule-shaped, biconvex tablets.	Canadian-labelled COVERSYL 4 mg Green rod-shaped biconvex scored tablets.

The Canadian COVERSYL carton labels contain information in both English and French.

The information in English on the carton and blister label artwork mostly complies with New Zealand labelling requirements with the exception of the following particulars:

- Absence of the medicine classification statement on the carton main label (the symbol “Pr” for Prescription is present instead)
- Absence of the drug substance name on the blister label. Medsafe does not consider this a safety risk for the proposed interim supply, on the basis that the information is present on the carton label.

CANADIAN COVERSYL carton (main panel) and blister labels:



A pack insert written in French and in English is included with the Canadian COVERSYL products. The information is consistent with product information approved in NZ for perindopril erbumine medicines however only Canadian Servier contact information is provided.

The prescribing and provision of patient counselling by Healthcare Professionals should continue in accordance with the New Zealand Data Sheet and Consumer Medicine Information for COVERSYL that can be accessed at www.medsafe.govt.nz. Both the Datasheet and Consumer Medicine Information are aligned with Servier's global Core Safety Datasheet.

Please report any suspected adverse events to the Centre for Adverse Reactions Monitoring (CARM) online at <https://nzphvc.otago.ac.nz/reporting> or by email to carmnz@otago.ac.nz. Alternatively, suspected adverse events may be reported to Healthcare Logistics (HCL) via telephone on +(64 9) 969 0705 or email at mtaylor@healthcarelogistics.co.nz

All supply or medical enquiries regarding COVERSYL may be directed to the distributor in New Zealand- Healthcare Logistics (HCL) via telephone on +(64 9) 969 0705 or email at mtaylor@healthcarelogistics.co.nz

Yours faithfully,



Dr. Maung Maung Oo

Medical Director

Servier Laboratories (New Zealand) Ltd