

09 June 2022

Dear Healthcare Professional,

## Supply of Canadian-labelled COVERSYL 2 mg, 4 mg and 8 mg perindopril erbumine tablets in New Zealand

Following the discontinuation of supply of APO-PERINDOPRIL products and another ACE-inhibitor- ZAPRIL cilazapril in New Zealand, PHARMAC has made a decision that COVERSYL will be the funded brand of perindopril tablets.

Medsafe has determined that Canadian-labelled COVERSYL can be supplied to the New Zealand market until supply of New Zealand-labelled COVERSYL product is available.

As such, COVERSYL 2 mg perindopril erbumine TT50-10867; COVERSYL 4 mg perindopril erbumine TT50-10867a and COVERSYL 8 mg perindopril erbumine TT50-10867b products have been granted Provisional Consent under section 23 of the Medicines Act 1981.

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

<b>APO-PERINDOPRIL 2 mg</b> White, round, biconvex tablets.	<b>Canadian-labelled COVERSYL 2 mg</b> White, round, biconvex tablets.
<b>APO-PERINDOPRIL 4 mg</b> White, capsule-shaped, biconvex tablets.	<b>Canadian-labelled COVERSYL 4 mg</b> Green rod-shaped biconvex scored tablets.
<b>ZAPRIL 5 mg tablets</b> Dark orange, capsule-shaped, biconvex tablets.	<b>Canadian-labelled COVERSYL 8 mg</b> Green round biconvex tablets with a Servier logo on one face and a heart logo on the other face



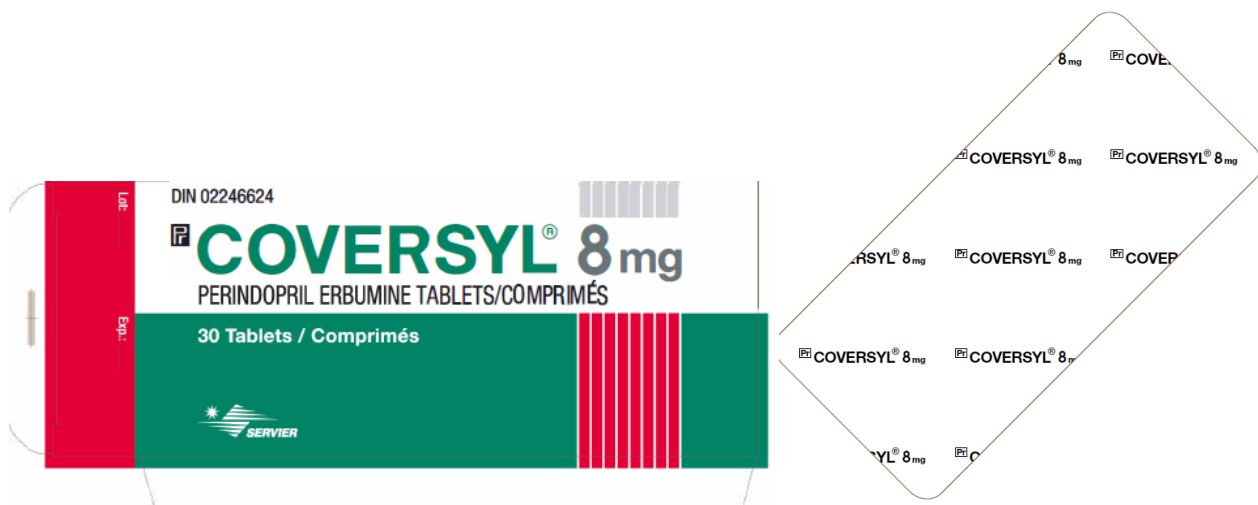
The Canadian COVERSYL carton labels contain information in both English and French. The information in English on the carton and blister label artwork mostly complies with New Zealand labelling requirements with the exception of the following particulars:

- 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.

As part of the Provisional Consent approval, Medsafe has granted Servier a labelling exemption to supply COVERSYL product in this non-compliant packaging.

### 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](http://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](mailto: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](mailto: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](mailto:mtaylor@healthcarelogistics.co.nz)

Yours faithfully,

**Dr. Maung Maung Oo**  
**Medical and Patient Affairs Director**  
**Servier Laboratories (New Zealand) Ltd**