



27<sup>th</sup> April 2023

Dear Healthcare Professional,

**Discontinuation of CAPOTEN captopril 5mg/mL oral liquid bottle AUST R: 68962 and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.**

Due to the discontinuation of the Australian registered CAPOTEN captopril 5mg/mL oral liquid bottle AUST R: 68962, Reach Pharmaceuticals has arranged the supply of an alternative product called **CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)**, registered and marketed in the United Kingdom.

**CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)** is not registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until 30<sup>th</sup> April 2024 for the following indications:

1. **HYPERTENSION:** captopril is indicated for the treatment of hypertension. In using captopril, consideration should be given to the risk of neutropenia/agranulocytosis. Captopril is effective alone and in combination with other antihypertensive agents, especially thiazide-type diuretics. The blood pressure lowering effects of captopril and thiazides are approximately additive.
2. **MYOCARDIAL INFARCTION:** Captopril is indicated to improve survival following myocardial infarction in clinically stable patients with left ventricular dysfunction manifested as an ejection fraction less than or equal to 40%, and to reduce the incidence of overt heart failure and subsequent hospitalisations for congestive heart failure in these patients. The efficacy data for the use of captopril following myocardial infarction are strongest for initiation of therapy beyond 3 days post-infarct.
3. **HEART FAILURE:** Captopril is indicated for the treatment of heart failure. In symptomatic patients it is recommended that captopril be administered together with a diuretic.
4. **DIABETIC NEPHROPATHY:** Captopril is indicated for the treatment of diabetic nephropathy in patients with Type 1 insulin dependent diabetes mellitus

**CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)** is registered and marketed in the United Kingdom (UK).

The S19A approved UK product is identical in active ingredient and strength to the Australian registered product. Please note the following information regarding differences between **CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)** and CAPOTEN captopril 5mg/mL oral liquid bottle AUST R: 68962:



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	<b>CAPOTEN captopril 5mg/mL oral liquid bottle AUST R: 68962</b>	<b>S19A product - CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)</b>
<b>Excipients</b>	citric acid disodium edetate hydrochloric acid purified water sodium benzoate sodium citrate dihydrate sodium hydroxide	Sodium benzoate (E211) Citric acid monohydrate (E330) Sodium citrate (E331) Disodium edetate Purified water
<b>Administration</b>	CAPOTEN (captopril) should be taken one hour before meals.  It is intended for administration mixed with a suitable drink (up to 100mL) such as water, fruit juice, tea, coffee or cola. The whole of the beverage should be drunk immediately after the addition of CAPOTEN oral solution.	Captopril may be taken before, during and after meals.
<b>Storage</b>	Store at 2°C to 8°C  Any solution remaining 28 days after the bottle is opened should be discarded.	Do not store above 30°C  Discard 21 days after first opening.

Please refer to the Australian Product Information for CAPOTEN captopril 5mg/mL oral liquid bottle AUST R: 68962: (available at <https://www.ebs.tga.gov.au>) for prescribing and recommended dosing for **CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)**.

### Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **CAPTOPRIL 25MG/5ML SUGAR FREE ORAL SOLUTION (SYRIMED)** should be reported by healthcare professionals and patients to our Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Reach Pharmaceuticals Medical Information can be contacted by phone on 1800 505 306 or via email at [medical@reach-pharma.com](mailto:medical@reach-pharma.com)

**For sales related enquiries, please contact us on [sales@reach-pharma.com](mailto:sales@reach-pharma.com) or call 0422 429 648.**



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We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

**Yours sincerely,**

Reach Pharmaceuticals Pty Ltd