

7 August, 2018

Dear Healthcare Professional

Shortage of Kaluril 5mg Tablets (Amiloride) Aust R 17652 and alternative supply arrangement under Section 19A of the Therapeutic Goods Act 1989

The Australian registered medicine, Kaluril 5mg Tablets (Amiloride) AUST R 17652, sponsored by Alphapharm Pty Ltd, is unavailable due to a manufacturing issue. Supply of Kaluril 5mg Tablets (Amiloride) is expected to resume on 31st October 2018.

HL Pharma Pty Ltd has arranged supply of an alternative product, Amiloride 5mg Tablets on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until 30 November 2018 for the following indication(s):

- Potassium- conserving agent; diuretic.
- Although Amiloride Hydrochloride may be used alone, its principal indication is as concurrent therapy with thiazides or more potent diuretics in order to conserve potassium during periods of vigorous diuresis and during long-term maintenance therapy.
- In congestive heart failure, Amiloride Hydrochloride may be effective alone, but its principal indication is for concomitant use in patients receiving thiazides or more potent diuretic agents.
- In hypertension, it is used as an adjunct to prolonged therapy with thiazides and similar agents to prevent potassium depletion.
- In hepatic cirrhosis with ascites, Amiloride Hydrochloride usually provides adequate diuresis, with diminished potassium loss and less risk of metabolic alkalosis, when used alone. It may be used with more potent diuretics when a greater diuresis is required while maintaining a more balanced serum electrolyte pattern.

Amiloride 5mg Tablets is registered and marketed in the United Kingdom.

Please note the following information regarding differences between Amiloride 5mg Tablets and Kaluril 5mg Tablets (Amiloride).

Kaluril, 5 mg tablet: pale yellow, flat bevelled edge, scored on one side, marked AR|5 on one side, G on reverse; Packed in bottles (HDPE) of 50 Tablets.

Amiloride 5mg tablet: Off white to creamy white, round, flat, uncoated tablet with bevelled edges and debossed with "C" and "G" on either side of break line and another side is plain. Packed in 1 x 28 tablets calendar pack in a carton. 20 micron hard-tempered aluminium foil, coated on the dull side with 6-7 GSM heat-seal lacquer and printed on the bright side; 250 micron rigid, green PVC Pharmaceutical Grade.

Amiloride 5mg tablet is a UK Prescription Only Medicine (POM) and has the same scheduling, formulation, dosage and indications as Kaluril 5mg tablet

PBS Reimbursement

UK registered Amiloride 5mg Tablets are not available for PBS reimbursement

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 Amiloride 5mg Tablets should be reported by healthcare professionals and patients to the HL Pharma on 03 9823 6228 or by email contact@hlpharma.com.au. Alternatively, this information can be reported to the TGA.

Please forward this information to relevant staff members in your organisation.

For further information, please contact HL Pharma on 03 9823 6228 or email contact@hlpharma.com.au

Yours sincerely



Ruth Macdonald
HL Pharma