



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of TOFRANIL 25 imipramine hydrochloride 25mg tablet blister pack (ARTG R: 60673)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you of the change in supply status of TOFRANIL 25 imipramine hydrochloride 25mg tablet blister pack (ARTG R: 60673).

The Australian registered medicine, TOFRANIL 25 imipramine hydrochloride 25mg tablet blister pack (AUST R: 60673), sponsored by Amdipharm Mercury Australia Pty Ltd, is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC)**. 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 **28th February 2023** for the following indications:

- Major depression.
- Nocturnal enuresis (from the age of 5 years onwards and provided the possibility of organic causes has first been excluded)

IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC) is indicated for treating nocturnal enuresis in children from 6 years and older. This is different to TOFRANIL 25 imipramine hydrochloride 25mg tablet blister pack (ARTG R: 60673), which is indicated for treating nocturnal enuresis in children from 5 years and older. Healthcare professionals should refer to the Australian approved Product Information (PI) of TOFRANIL 25 imipramine hydrochloride 25mg tablet blister pack (ARTG R: 60673) for recommended dosing for the above indications, available from <https://www.ebs.tga.gov.au/>.

IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC) is registered and marketed in the USA by Leading Pharma LLC and are packaged in English language. **IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC)** is available in bottle packs of 100 tablets.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC)** must be reported by healthcare professionals, pharmacists and patients to Pro Pharmaceuticals Group on 1300 077 674 or email regulatory@propg.com.au. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

Any product complaints with **IMIPRAMINE HYDROCHLORIDE TABLETS USP, 25 MG 100 TABLETS (LEADING PHARMA LLC)** should be reported to Pro Pharmaceuticals Group on 1300 077 674 or email regulatory@propg.com.au

For any orders, please visit our Pro Pharmaceuticals Group website www.propg.com.au or contact us on phone 1300 077 674 or email orders@propg.com.au

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

For further information, please contact Pro Pharmaceuticals Group on 1300 077 674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group

