

02 June 2022

Dear Healthcare Professional

Discontinuation of NARDIL phenelzine 15mg (as sulfate) tablet bottle and alternate supply arrangement under Section 19A of the Therapeutic Goods Act

The Australian registered medicine, **NARDIL phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600)**, sponsored by Link Pharmaceuticals has been discontinued.

Medsurge has been able to arrange for the supply of **NARDIL* Phenelzine Sulfate 15mg Tablets USP bottle (Canada)** as an alternative product on a temporary basis. This product 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 September 2023** for the following indication:

For the treatment of major depression.

Phenelzine Sulfate Tablets should rarely be the first antidepressant drug used. Rather it is more suitable for use with patients who have failed to respond to the drugs more commonly used for these conditions.

The Australian registered product NARDIL phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600) and the Canadian product NARDIL* Phenelzine Sulfate 15mg Tablets USP bottle (Canada) contain the same active ingredient and strength. A comparison table of differences between is given below:

| | ARTG product | S19A Product |
|-------------------|---|---|
| | NARDIL phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600) | NARDIL* Phenelzine Sulfate 15mg Tablets USP bottle (Canada) |
| Excipients | Mannitol Povidone Starch-maize Magnesium stearate Opadry 20A25096 Red | crosscarmellose sodium editate disodium magnesium stearate mannitol opadry orange povidone |
| Pack size | Bottle packs of 100 tablets | Bottle packs of 60 tablets |
| Storage | Store at 2°C to 8°C (Refrigerate. Do not freeze) | Store at controlled room temperature 15 - 30°C. Protect from heat and moisture. |

NARDIL* Phenelzine Sulfate 15mg Tablets USP bottle (Canada) is registered and marketed in Canada by Erfa Canada 2012 Inc. Therefore, all labelling and package leaflet are in English. Medsurge recommends that healthcare professionals refer to the Australian Product Information for recommended dosing.

Any adverse events which are experienced with **NARDIL* Phenzine Sulfate 15mg Tablets USP bottle (Canada)**, should be reported by healthcare professionals and to Medsurge on 1300 788 261 or email sales@medsurge.com.au. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **NARDIL* Phenzine Sulfate 15mg Tablets USP bottle (Canada)**, should be reported to Medsurge on 1300 788 261 or email sales@medsurge.com.au.

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

For further information, please contact Medsurge Healthcare on 1300 788 261 or email sales@medsurge.com.au

Yours Sincerely,

Regulatory and Quality Associate
Medsurge Healthcare