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10 February 2021

Dear Healthcare Professional,

**Shortage of Nardil phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600) and alternative supply arrangement under Section 19A of the Therapeutic Goods Act 1989**

As you may be aware, the Australian registered medicine, **Nardil phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600)**, sponsored by Link Medical Products Pty Ltd, has been discontinued from the Australian market. To address this medicine shortage, Generic Health Pty Ltd has been able to arrange supply of an alternative product, **Phenelzine Sulfate USP 15 mg Tablets (Lupin Pharmaceuticals)**, on a temporary basis.

This product is NOT registered in Australia; however, supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **30 September 2021** for the following indication(s):

- For the treatment of depression.
- Phenelzine sulfate 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.

**To dispensing pharmacists**

Please advise all patients the difference in storage conditions between the Australian registered Nardil and the Section 19A product - **Phenelzine Sulfate USP 15mg tablets (Lupin Pharmaceuticals)**.

Please provide the following documents to all patients with each dispensing of **Phenelzine Sulfate USP 15mg tablets (Lupin Pharmaceuticals)**:

- 1) a copy of the attached Dear Patient/Carer letter and
- 2) the Australian **Nardil phenelzine 15mg (as sulfate) tablet** CMI available at <https://www.ebs.tga.gov.au/> (or via the URL below).

**URL:** <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-CMI-03336-3&d=202008201016933>

**Phenelzine Sulfate USP 15 mg Tablets (Lupin Pharmaceuticals)** is registered and marketed in the United States of America by Lupin Pharmaceuticals, Inc. and therefore all labelling is in English. Generic Health Pty Ltd recommends that healthcare professionals refer to the Australian



Product Information of **Nardil phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600)** for recommended dosing.

Please note the following similarities and differences between **Nardil Phenelzine 15mg (as sulfate) tablet bottle (AUST R 93600)** and **Phenelzine Sulfate USP 15 mg Tablets (Lupin Pharmaceuticals)**, to be supplied under section 19A (referred as the S19A product below). The two products differ in their storage conditions, pack size and excipients.

	<b>Nardil (Phenelzine Sulfate) Tablets, 15 mg (AUST R 93600)</b>	<b>Phenelzine Sulfate Tablets, USP 15 mg (Lupin Pharmaceuticals) (S19A product)</b>
<b>Storage conditions:</b>	Store at 2°C to 8°C (Refrigerate. Do not freeze)	Store at 20 to 25 °C
<b>Pack size</b>	Bottles of 100 tablets	Bottles of 60 tablets
<b>Excipients</b>	erythrosine; hyprolose; hypromellose; magnesium stearate, maize starch; mannitol, polyvinyl acetate phthalate; povidone, purified talc; stearic acid sunset yellow FCF and titanium dioxide	mannitol; colloidal silicon dioxide; povidone; edetate disodium; magnesium stearate; purified water; polyvinyl alcohol part hydrolyzed; polyethylene glycol-3350; FD&C yellow # 6; talc and titanium dioxide

### **PBS Reimbursement**

This product is PBS listed.

### **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 **Phenelzine Sulfate Tablets, USP 15 mg**, should be reported by healthcare professionals and patients to the Generic Health Pty Ltd on (03) 9809 7900 or by email ([qaproductsafety@generichealth.com.au](mailto:qaproductsafety@generichealth.com.au)). Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>

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

For customer support or assistance with medical enquiries, please feel free to contact Generic Health, as follows:

	<b>Contact details</b>	<b>Type of queries</b>
<b>Customer Service Team</b>	03 9809 7900	Customer Support including product availability
<b>Medical Information Team</b>	03 9809 7900 or qaproductsafety@generichealth.com.au	Medical enquiries

Yours sincerely

**Medical Information Team**  
**Generic Health Pty Ltd (Lupin Group Company)**