

30th August 2023

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Dear Healthcare Professional

Shortage of LUMIN 20 Mianserin hydrochloride 20mg tablet blister pack (ARTG 55273) and alternative supply arrangement under section 19A of the Therapeutic Goods Act 1989

The Australian registered medicine, **LUMIN 20 Mianserin hydrochloride 20mg tablet blister pack (ARTG 55273)** sponsored by Alphapharm Pty Ltd is currently unavailable or in short supply.

LINK has been able to arrange supply of an alternative product **Mianserin 10mg tablets (Mylan)** 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 **31st October 2023** for the following indication(s):

For the treatment of major depression.

Mianserin 10mg tablets (Mylan) is registered and marketed in the United Kingdom.

Please note the following information regarding differences between **LUMIN 20 Mianserin hydrochloride 20mg tablet blister pack (ARTG 55273)** and **Mianserin 10mg tablets (Mylan)**.

	AU registered medicine Lumin (Mianserin hydrochloride) ARTG 55273	Section 19A approved medicine Mianserin 10mg Tablet (Mylan)
Strength	20mg	10mg
Excipients	Pregelatinised maize starch Colloidal anhydrous silica Microcrystalline cellulose Calcium hydrogen phosphate Magnesium stearate Opadry White Y-1-7000 Carnauba wax.	Maize starch, pregelatinised Silica, colloidal anhydrous Cellulose, microcrystalline Calcium hydrogen phosphate Magnesium stearate The film coat contains: Talc Titanium dioxide (E171) Hypromellose Macrogol 400
Indications	For the treatment of major depression.	Mianserin Tablets are indicated for symptoms of depressive illness.
Administration details	Lumin tablets should be taken orally between meals, preferably with a little fluid, and swallowed without chewing.	The daily dose can be taken either in divided doses or as a single dose at night (due to the favourable effect on sleep).

	<p>Use in Children and Adolescents (< 18 years of age) Lumin should not be used in children and adolescents under the age of 18 years.</p> <p>Adults The initial dosage of Lumin should be judged individually. It is recommended that treatment begin with a daily dose of 30 mg given in three divided doses or as a single bedtime dose and be adjusted weekly in the light of the clinical response. The effective daily dose for adult patients usually lies between 30 mg and 90 mg (average 60 mg) in divided doses or as a single bedtime dose. A maximum daily dose of 120 mg should not be exceeded. It is often advantageous to maintain antidepressant treatment for several months after initial clinical improvement has occurred.</p> <p>Elderly Initially, not more than 30 mg daily and increased slowly under close supervision. A reduced dose may also be required for maintenance, as hepatic, renal or cardiovascular function may be impaired. Pharmacokinetic studies of mianserin in the elderly patient suggest a longer half-life and slower metabolic clearance. This implies that a single night-time dose of mianserin hydrochloride should be preferred to divided doses in the elderly patient.</p>	<p>It is often advantageous to maintain antidepressant treatment for several months after clinical improvement has occurred. In order to ensure an optimal antidepressant effect the dosage of mianserin should not be reduced.</p> <p>Adults Treatment should usually commence with 30 mg or 40 mg mianserin per day increasing gradually as necessary. The effective dosage usually lies between 30 mg and 90 mg. Divided doses of up to 200 mg are well tolerated.</p> <p>Older people The use of mianserin is restricted to patients over 65 who:</p> <ul style="list-style-type: none"> • do not respond to other antidepressant drugs • have glaucoma • have prostatic hypertrophy <p>Not more than 30 mg a day initially. A lower-than-normal maintenance dose may be sufficient to produce a satisfactory clinical response. Pharmacokinetic studies of mianserin in the elderly patient suggest a longer half-life and slower metabolic clearance. This information implies that a single night-time dose of mianserin should be preferable to the divided dose in older people; in addition a lower than normal maintenance dose may be sufficient to produce a satisfactory clinical response.</p> <p>Paediatric population Mianserin should not be used in the treatment of children and adolescents under the age of 18 years. Method of administration For oral use. The tablets should be swallowed whole without chewing.</p>
Pack size	50 Tablets	28 Tablets
Storage conditions	Store below 30°C. In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.	Store below 25°C. Protect from light.

Please refer to the Australian Product Information for **LUMIN 20 Mianserin hydrochloride 20mg tablet blister pack (ARTG 55273)** available at <https://www.ebs.tga.gov.au> when prescribing and administering **Mianserin 10mg tablets (Mylan)**.

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 **Mianserin 10mg tablets (Mylan)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at PV@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Any product complaints regarding **Mianserin 10mg tablets (Mylan)** should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation.
For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully

Kay Roweth

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Link Healthcare