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27thAugust 2019

Dear Healthcare Professional,

RE: Shortage of Mianserin hydrochloride 10mg tablet blister pack and alternate supply arrangement under Section 19A of the Therapeutic Goods Act

The Australian registered medicines, **LUMIN 10 Mianserin hydrochloride 10mg tablet blister pack (Aust R 55272)** and **LUMIN 20 Mianserin hydrochloride 20mg tablet blister pack (Aust R 55273)**, sponsored by Alphapharm Pty Ltd, are unavailable.

Medsurge has been able to arrange for supply of alternative product **Mianserin 10mg film coated tablets (UK)**, 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 **29thFebruary 2020** for the following indication(s):

For the treatment of major depression

Please see below a comparison table of major differences between the Australian registered **LUMIN 10 Mianserin hydrochloride 10mg tablet blister pack** and the Section 19A product **Mianserin 10mg film-coated tablets (UK)**.

	ARTG product (LUMIN 10 Mianserin hydrochloride 10mg tablet blister pack)	S19A product (Mianserin 10mg film-coated tablets (UK))
Dosage	<p>Lumin tablets should be taken orally between meals, preferably with a little fluid, and swallowed without chewing.</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</p>	<p>Posology The daily dose can be taken either in divided doses or as a single dose at night (due to the favourable effect on sleep). 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</p>

	<p>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>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>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><i>Older people</i> 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><i>Paediatric population</i> Mianserin should not be used in the treatment of children and adolescents under the age of 18 years.</p>
Excipients	<p>Pregelatinised maize starch Colloidal anhydrous silica Microcrystalline cellulose Calcium hydrogen phosphate Magnesium stearate Opadry White Y-1-7000 Carnauba wax.</p>	<p>Maize starch, pregelatinised Silica, colloidal anhydrous Cellulose, microcrystalline Calcium hydrogen phosphate Magnesium stearate The film coat contains: Talc Titanium dioxide (E171) Hypromellose Macrogol 400</p>
Storage	Store below 30°C	Store below 25°C. Protect from light.
Pack size	Packs of 50 tablets	Blister pack of 28 tablets

Mianserin 10mg film coated tablets (UK) is registered and marketed in UK by Mylan and therefore all labelling is in English. Medsurge recommends that healthcare professionals refer to the Australian Product Information for recommended dosing.

Any adverse events which are experienced with **Mianserin 10mg film coated tablets (UK)** should be reported by healthcare professionals, pharmacists and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Medsurge on 1300 788 261 or email sales@medsurge.com.au.

Any product complaints **Mianserin 10mg film coated tablets (UK)**, 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 Affairs Manager
Medsurge Healthcare