

Pro Pharmaceuticals Group Pty LTD ABN: 20 605 457 430 www.propg.com.au

Dear Healthcare Professional,

## Shortage of LANOXIN ADULT digoxin 500microgram/2mL injection ampoule (ARTG 11106)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of LANOXIN ADULT digoxin 500microgram/2mL injection ampoule (ARTG 11106) in Australia.

The Australian registered medicine, LANOXIN ADULT digoxin 500microgram/2mL injection ampoule (ARTG 11106), sponsored Aspen is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **LANOXIN** digoxin **0.5mg** injection ampoule **(UK).** 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**<sup>th</sup> **September 2023** for the following indication(s):

Congestive heart failure - Lanoxin is useful regardless of whether the failure is predominantly of the left or right ventricle or involves both sides of the heart. It is particularly useful in heart failure resulting from chronic overload (hypertension, valvular lesions, atherosclerotic heart disease) in which the supply of energy is not impaired. Lanoxin does not cause major benefit in situations in which the metabolic energy supply is compromised as in thyrotoxicosis, hypoxia, and severe thiamine deficiency. Atrial fibrillation - Because Lanoxin depresses conduction in the atrioventricular bundle, producing a slower ventricular beat, it is valuable in atrial fibrillation. It will frequently convert atrial flutter into fibrillation, and, upon withdrawal of the drug, normal sinus rhythm may be restored.

**Paroxysmal atrial tachycardia** - Lanoxin may relieve or prevent an attack, but its use in paroxysmal ventricular tachycardia is dangerous.

**LANOXIN digoxin 0.5mg injection ampoule (UK)** is registered and marketed in UK by Aspen. It is identical in active ingredient, strength and composition to the Australian registered product and all labelling is in English.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information and the Australian injectable drugs handbook for recommended dosing and preparation instructions.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with LANOXIN digoxin 0.5mg injection ampoule (UK) must be reported by healthcare professionals, pharmacists, and patients to the TGA at <a href="https://www.tga.gov.au/reporting-problems">https://www.tga.gov.au/reporting-problems</a> or to Pro Pharmaceuticals Group on 1300077674 or email <a href="mailto:regulatory@propg.com.au">regulatory@propg.com.au</a>

Any product complaints with **LANOXIN digoxin 0.5mg injection ampoule (UK)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 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 1300077674 or email <a href="mailto:info@propg.com.au">info@propg.com.au</a>

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group

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