5 September 2023

Shortage of LONITEN minoxidil 10mg tablets and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **LONITEN minoxidil 10mg tablets (AUST R 12309),** ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

Minoxidil 10mg tablets (Roma Pharmaceuticals), are NOT registered in Australia and supply is granted under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **31 October 2023.**

Minoxidil 10mg tablets (Roma Pharmaceuticals), are approved for use under Section 19A for the following indications:

> *As adjunctive therapy in adults with severe refractory hypertension which has failed to respond to extensive multiple therapy.*
>
> *When used in combination with an accompanying diuretic and beta-blocker, minoxidil MINOXIDIL has been shown to reverse encephalopathy and retinopathy in severe hypertensives.*

The s19A approved UK product is identical in active ingredient and strength to the Australian registered product. The two products differ in their pack sizes. The differences are noted below:

	ARTG product LONITEN minoxidil 10mg tablets (AUST R 12309).	**S19A product** Minoxidil 10mg tablets (Roma Pharmaceuticals)
Nature and contents of container	The tablets are supplied in HDPE bottles of 100.	Minoxidil Tablets are packed in opaque PVC/PVDC/ALU blisters. Each blister contains 10 tablets. Pack size: 60 tablets.

Minoxidil 10mg tablets (Roma Pharmaceuticals), are registered in the United Kingdom and are packaged in English language. For dosing and administration information, please refer to the Australian Product Information for LONITEN® minoxidil 10mg tablets **(**AUST R 12309) available at https://www.ebs.tga.gov.au/

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 **Minoxidil 10mg tablets (Roma Pharmaceuticals),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at sas@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

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

For further information, please contact ORSPEC Pharma on 024 339 4239 or email sas@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma