25 January 2023

Shortage of DITROPAN oxybutynin hydrochloride 5mg 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 **DITROPAN oxybutynin hydrochloride 5mg tablets (AUST R 48965).** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited) are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **28 February 2023.**

Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited), are approved for use under Section 19A for the following indications:

Treatment of detrusor over-activity where conservative measures have failed.

Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited) are registered in the United Kingdom (UK) and are packaged in English language. The UK product is identical in active ingredient and strength to the Australian registered product.

A comparison table of differences between is given below:

	DITROPAN oxybutynin hydrochloride 5mg tablet (ARTG 48965	**Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited)**
Excipients	Calcium stearate Microcrystalline cellulose Lactose Brilliant blue FCF aluminium lake.	Crospovidone Microcrystalline cellulose Lactose monohydrate Magnesium stearate Indigo carmine aluminium lake (E132)
Presentation	Light blue, round, single scored uncoated tablet, blank on both sides	Light blue circular, flat bevelled edge tablets with a diameter of approximately 7.5 mm, marked

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		'OXB 5' on one side with a breakline on the reverse.
Pack size	Bottle containing 100 tablets	Pack with blister of 84 tablets

For dosing and administration information, please refer to the Australian Product Information for Ditropan oxybutynin 5mg tablets 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 **Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited)** 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