



4 August 2022

**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 **31 January 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:

	<b>DITROPAN oxybutynin hydrochloride 5mg tablet (ARTG 48965)</b>	<b>Oxybutynin hydrochloride 5mg tablets (Niche Generics Limited)</b>
<b>Excipients</b>	Calcium stearate Microcrystalline cellulose Lactose Brilliant blue FCF aluminium lake.	Crospovidone Microcrystalline cellulose Lactose monohydrate Magnesium stearate Indigo carmine aluminium lake (E132)
<b>Presentation</b>	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

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

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](mailto: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](mailto:sas@orspecpharma.com).

Yours sincerely,



Deon Scheepers  
Managing Director  
ORSPEC Pharma