



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD  
 ABN: 20 605 457 430  
[www.propg.com.au](http://www.propg.com.au)

Dear Healthcare Professional,

**Shortage of DITROPAN oxybutynin hydrochloride 5mg tablet bottle (ARTG 48965) and alternate supply arrangement under Section 19A of the Therapeutic Goods Act**

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of DITROPAN oxybutynin hydrochloride 5mg tablet bottle in Australia.

The Australian registered medicine, **DITROPAN oxybutynin hydrochloride 5mg tablet bottle AUST R: 48965** sponsored by Sanofi-Aventis Australia Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of **Oxybutynin Chloride Tablets, USP 5mg (Novitium Pharma, USA)** as an alternative product 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 **31<sup>st</sup> January 2023** for the following indication(s):

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

**Oxybutynin Chloride Tablets, USP 5mg (Novitium Pharma, USA)** is registered and marketed in the USA by **Novitium Pharma, USA**.

A comparison table of differences between Australian registered product DITROPAN oxybutynin hydrochloride 5mg tablet bottle (ARTG 48965) and the USA product Oxybutynin Chloride Tablets, USP 5mg (Novitium Pharma, USA) is given below.

|                     | <b>ARTG product<br/>DITROPAN oxybutynin hydrochloride 5mg<br/>tablet (ARTG 48965)</b>           | <b>S19A product<br/>OXYBUTYNIN CHLORIDE 5mg Tablets USP<br/>(Novitium Pharma -USA)</b>  |
|---------------------|---|---|
| <b>Excipients</b>   | Calcium stearate<br>Microcrystalline cellulose<br>Lactose<br>Brilliant blue FCF aluminium lake. | Anhydrous lactose, croscarmellose sodium,<br>lactose monohydrate, magnesium stearate,<br>microcrystalline cellulose.<br>Anhydrous lactose, croscarmellose |
| <b>Presentation</b> | Light blue, round, single scored uncoated tablet,<br>blank on both sides                        | White, round, biconvex tablets debossed with<br>"n005" on one side and bisect on the other<br>side.   |

**OXYBUTYNIN CHLORIDE 5mg Tablets USP (Novitium Pharma -USA)** contains **lactose**. This information is not printed on the carton labels. Healthcare professionals should advise their patients upon dispensing **OXYBUTYNIN CHLORIDE 5mg Tablets USP (Novitium Pharma -USA)** that this product contains **lactose**.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing.

**Adverse Event Reporting**

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Oxybutynin Chloride Tablets, USP 5mg (Novitium Pharma, USA)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300 077674 or email [regulatory@propg.com.au](mailto:regulatory@propg.com.au).

Any product complaints with **Oxybutynin Chloride Tablets, USP 5mg (Novitium Pharma, USA)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email [regulatory@propg.com.au](mailto:regulatory@propg.com.au)

For any orders, please contact Pro Pharmaceuticals Group on 1300 077674 or email [orders@propg.com.au](mailto:orders@propg.com.au)

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

For further information, please contact Pro Pharmaceuticals Group on 1300 077 674 or email [info@propg.com.au](mailto:info@propg.com.au)

Sincerely,  
 Sandip Manku – Director Pro Pharmaceuticals Group

