

31 March 2022

**RE: Discontinuation of Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG 48529) (in April 2015) and alternative supply arrangement under Section 19A of the Therapeutic Goods Act.**

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Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the discontinuation, in 2015, of the Australian registered **Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG 48529)**, LINK has arranged the supply of an alternative product, **ATROPINE SULFATE 1mg/5mL, solution for injection in pre-filled syringe (Laboratoire Aguettant)** (5 mL pre-filled syringe in pack sizes of 1 or 10).

This product is registered in the UK and has been supplied, since July 2013, under multiple longstanding approvals granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989*. Approval to Link, to supply under section 19A, will be granted until **31 March 2024** for the following indications:

*Atropine sulfate Aguettant 0.2 mg/mL, solution for injection in pre-filled syringe is indicated in adults only.*

- *As a pre-anaesthetic medication to prevent vagal reactions associated with tracheal intubation and surgical manipulation*
- *To limit the muscarinic effects of neostigmine, when given postsurgically to counteract non-depolarising muscle relaxants*
- *Treatment of hemodynamically compromising bradycardia and/or atrioventricular block due to excessive vagal tone in emergency situation*
- *Cardiopulmonary resuscitation: to treat symptomatic bradycardia and AV block*
- *As antidote following overdose or poisoning with acetylcholinesterase-inhibitors e.g. anticholinesterases, organophosphorus, carbamates and muscarinic mushrooms*

Please note the following information regarding the differences between **Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG 48529)** and **ATROPINE SULFATE 1mg/5mL, solution for injection in pre-filled syringe (Laboratoire Aguettant)** to be supplied under Section 19A (referred as the s19A product below):

	<b>Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG product)</b>	<b>ATROPINE SULFATE 1mg/5mL, solution for injection in pre-filled syringe (Laboratoire Aguettant) (s19A product)</b>
<b>Concentration</b>	1mg/10ml injection	1mg/5ml Injection
<b>Route of Administration</b>	Intravenous Intramuscular Subcutaneous	Intravenous Intramuscular
<b>Excipients</b>	sodium chloride	Sodium chloride

	sodium citrate citric acid monohydrate.	Concentrated hydrochloric acid (for pH adjustment) Water for injections
<b>Paediatric use</b>	Please refer to the Australian Product Information (PI) for <b>Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG 48529)</b>	The product is approved <b>for use in adults only</b> .  The pre-filled syringe is not adapted to the administration in paediatric population; the graduation does not permit accurate measurement.
<b>Storage</b>	Store below 25°C. Protect from light.	This medicinal product does not require any special storage conditions
<b>Pack size</b>	Carton of 1x10ml syringe	Carton of 1x5ml and 10x5ml syringes

Please refer to the enclosed package insert (UK Summary of Product Characteristics) for **ATROPINE SULFATE 1mg/5mL, solution for injection in pre-filled syringe (Laboratoire Aguettant)** and the Australian Product Information for **Min-I-Jet Atropine Sulphate 1mg/10mL injection syringe vial (ARTG 48529)** for usage and safety information. The Australian PI is available at:  
<http://www.tga.gov.au/picmi-search-facility>

#### 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 **ATROPINE SULFATE 1mg/5mL, solution for injection in pre-filled syringe (Laboratoire Aguettant)** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at [medinfo@linkhealthcare.com.au](mailto:medinfo@linkhealthcare.com.au). This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

#### Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at [customerservice@linkhealthcare.com.au](mailto:customerservice@linkhealthcare.com.au).

We would appreciate if you could distribute this information to those in your organisation who would be affected by the discontinuation of the Australian registered Atropine sulfate Min-I-Jet.

Yours sincerely,



Charlotte Griffin  
Medicine Access Associate