MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Isoniazid (Arrotex®) 100 mg tablet – 25 June 2024	
Details of affected product(s)	Isoniazid (Arrotex®) 100 mg tablet (AUST R: 13455)
Reason for communication	Disruption to supply
Date issue made apparent	May 2024
Estimated resolution date	30 August 2024

Main indications and use

Isoniazid is indicated for the treatment of pulmonary and extrapulmonary tuberculosis in combination with other antitubercular agents. It can also be used off-label in Tuberculosis Preventative Therapy (TPT) either as monotherapy or in combination with a rifamycin (rifampicin or rifapentine).

Situation

There is a disruption to the supply of isoniazid (Arrotex®) 100 mg tablet until 30 August 2024 due to manufacturing issues.

Alternative agents

At the time of publication, an international alternative has been approved for supply in Australia until **31 October 2024** under Section 19A (S19A) of the *Therapeutic Goods Act 1989* and is available for purchase via Link.

- Isoniazid tablets, USP 100 mg (Teva) from the United States of America (USA). See TGA S19A approvals database for further information.

If required, further alternatives may be available under the Special Access Scheme.

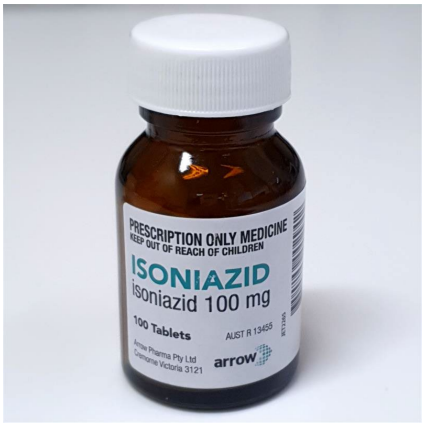
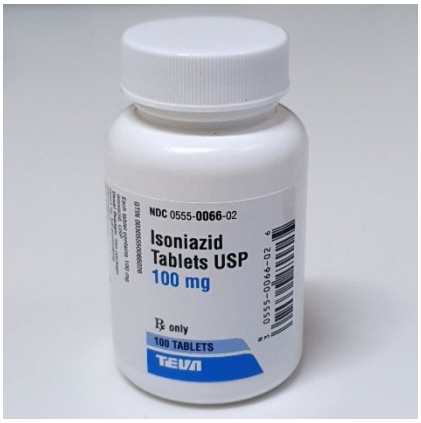
Precautions, safety issues and other considerations associated with alternative products

- The S19A alternative is identical in active ingredient and strength to the Australian registered product. There are differences in storage conditions, excipients, and presentation. See **Table 1** on the next page for a comparison.
- There is also a difference in classification of the pregnancy category between the Australian registered product (assigned by the TGA as Category A) and the S19A alternative from the USA (assigned by the Food and Drugs Administration [FDA] as Category C). An expert panel convened by the NSW Tuberculosis Program (Health Protection NSW) has **endorsed use of the Section 19A alternative during pregnancy** as the difference between the TGA and FDA assigned categories is a theoretical distinction that should not change treatment recommendations. As with all medicines used in pregnancy however, a risk vs. benefit assessment should be completed in consultation with the patient with consideration given to all relevant factors. Ensure pregnant women supplied the Section 19A alternative receive appropriate education to alleviate any concerns about appropriateness for use.
- It is recommended that facilities review their local guidelines/policies containing isoniazid given the disruption to supply and limit supply to a maximum quantity of **one month** at a time for outpatients, and **three days** for inpatients, to allow greater control of supply.
- Where the S19A alternative is used, clinicians should inform patients of the change in brand.

Impacts to this communication on clinical practice

- Actions to address the disruption to the supply of isoniazid (Arrotex®) should be planned and implemented at a local level by the Drug and Therapeutics Committee in consultation with the relevant clinicians and stakeholders (including Tuberculosis Clinics).
- Before supplying the S19A alternative, facilities should consider the above precautions and safety issues in addition to individual patient needs.

Table 1. Comparison of isoniazid products

	ARTG Product Isoniazid 100 mg tablet (Arrotex®)	S19A product Isoniazid tablets, USP 100 mg (Teva, USA)
Pregnancy category	TGA Category A	FDA Category C
Storage conditions	Store below 25°C Protect from light and moisture	Store at 20° to 25°C Protect from light and moisture
Excipients	Microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycollate, gelatin, propyl hydroxybenzoate, lactose monohydrate, calcium stearate, maize starch, sodium benzoate, wheat starch, dextrin	Colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil, microcrystalline cellulose, pregelatinized corn starch, talc
Presentation (packaging)		

Associated regulatory or policy issues

PD2022_032 Medication Handling

PD2024_016 System-level patient safety risks: Response co-ordination and communication

Key contacts

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