



6th June 2023

Shortage of CYTOTEK Misoprostol 200 microgram tablet blister pack 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 **CYTOTEK Misoprostol 200 microgram tablet blister pack (AUST R 63983)**, ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Misoprostol 200 microgram tablet bottle (ANI) are NOT registered in Australia and supply is granted under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until **31 January 2024**.

Misoprostol 200 microgram tablet bottle (ANI) are approved for use under Section 19A for the following indications:

- *The prevention of gastric ulceration in patients in whom NSAID therapy is essential and who have been assessed at high risk of gastric ulceration, or the complications of gastric ulceration.*

Misoprostol 200 microgram tablet bottle (ANI) are registered in the United States and are packaged in English language. Please note the following similarities and differences between, **CYTOTEK Misoprostol 200 microgram tablet blister pack (AUST R 63983)** and **Misoprostol 200 microgram tablet bottle (ANI)** to be supplied under section 19A:

	CYTOTEK Misoprostol 200 microgram tablet blister pack (AUST R 63983)	Misoprostol 200 microgram tablet bottle (ANI)
Excipient Ingredients	<ul style="list-style-type: none">• Microcrystalline cellulose• Hypromellose• Sodium starch glycolate• Hydrogenated castor oil	<ul style="list-style-type: none">• Hydrogenated vegetable oil• Hypromellose• Microcrystalline cellulose• Sodium starch glycolate
Presentation	Blister pack of 120 tablets	Bottle of 60 and 100 tablets

Storage	Store below 25° C and protect from moisture.	Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) Store in a dry area.
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For dosing and administration information for the above approved indication, please refer to the Australian Product Information for **CYTOTEC Misoprostol 200 microgram tablet blister pack (AUST R 63983)** 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 **Misoprostol 200 microgram tablet bottle (ANI)**, 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