



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	384574	METRONIDAZOLE NORIDEM, metronidazole 500mg/100mL solution for injection bottle
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Interpharma Pty Ltd	
<b>Postal Address</b>	PO Box 115, MANLY, NSW, 1655 Australia	
<b>ARTG Start Date</b>	27/03/2023	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Drug Safety Evaluation Branch	

### Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

### Products

#### 1 . METRONIDAZOLE NORIDEM, metronidazole 500mg/100mL solution for injection bottle

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/10/2023
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#### Permitted Indications

No Permitted Indications included on Record

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

Treatment of severe anaerobic infection when oral medication is not possible or is contraindicated, when immediate antianaerobic therapy is required. Metronidazole may be used prophylactically to prevent infection of the surgical site which may have been contaminated or potentially contaminated with anaerobic organisms. Procedures in which this may be assumed to have happened include appendectomy, colonic surgery, vaginal hysterectomy, abdominal surgery in the presence of anaerobes in the peritoneal cavity and surgery performed in the presence of anaerobic septicaemia.

#### Warnings

See Product Information and Consumer Medicine Information for this product

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	PP	36 Months	Store below 30 degrees Celsius	Not recorded	Protect from Light

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
20 bottles	(S4) Prescription Only Medicine

#### Components

##### 1 . METRONIDAZOLE NORIDEM, metronidazole 500mg/100mL solution for injection bottle

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	Clear solution, free of visible particles.

#### Active Ingredients

metronidazole	500 mg
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#### Other Ingredients (Excipients)

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citric acid monohydrate

dibasic sodium phosphate dodecahydrate

sodium chloride

water for injections

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