## METRONIDAZOLE NORIDEM

#### **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I being given METRONIDAZOLE NORIDEM?

**METRONIDAZOLE NORIDEM** contains the active ingredient metronidazole. **METRONIDAZOLE NORIDEM** is used to treat serious infections caused by bacteria and other organisms and prevent certain infections that may occur during surgery.

For more information, see Section 1. Why am I being given METRONIDAZOLE NORIDEM? in the full CMI.

#### 2. What should I know before I am given METRONIDAZOLE NORIDEM?

Do not use if you have ever had an allergic reaction to METRONIDAZOLE or any of the ingredients listed at the end of the CMI, or have Cockayne syndrome.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given METRONIDAZOLE NORIDEM? in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with **METRONIDAZOLE NORIDEM** and affect how it works.

A list of these medicines is in section 3. What if I am taking other medicines? in the full CMI.

#### 4. How is METRONIDAZOLE NORIDEM given?

METRONIDAZOLE NORIDEM is given as injection into a vein. METRONIDAZOLE NORIDEM should only be given by a doctor or nurse.

More instructions can be found in Section 4. How is METRONIDAZOLE NORIDEM given? in the full CMI.

## 5. What should I know while being given METRONIDAZOLE NORIDEM?

Things you should do	Tell any doctor, dentist or pharmacist you visit that you are being given METRONIDAZOLE NORIDEM, especially if the following apply:-	
	If you become pregnant while you are being treated with METRONIDAZOLE NORIDEM.	
	If the symptoms of your infection do not improve or if they become worse.	
	• If you get severe diarrhoea. Do this even if it occurs several weeks after METRONIDAZOLE NORIDEM has been stopped.	
	If you get a sore white mouth or tongue while using or soon after stopping METRONIDAZOLE NORIDEM.	
	If you get vaginal itching or discharge.	
	• If you are using METRONIDAZOLE NORIDEM for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.	
	If you need to have any blood tests.	
Driving or using machines	METRONIDAZOLE NORIDEM may cause dizziness, confusion, hallucination (hearing or seeing strange or unusual things), convulsions ("fits") or affect how you see things. If affected to do drive or operate machinery.	
Drinking alcohol	Do not drink any alcohol or any alcoholic drinks while being treated with METRONIDAZOLE NORIDEM and for at least three days after stopping METRONIDAZOLE NORIDEM.	
Looking after your medicine	METRONIDAZOLE NORIDEM will usually be stored in the pharmacy or on the ward. The infusion is kept in a cool dry place, protected from light, where the temperature stays below 30°C.	

For more information, see Section 5. What should I know while using METRONIDAZOLE NORIDEM? in the full CMI.

#### 6. Are there any side effects?

Some common side affects you might experience include nausea, vomiting, abdominal cramps, joint pains, oral or vaginal thrush, constipation or diarrhoea. More serious side effects may include hypersensitivity reactions which may include rash, swelling of face, lips or mouth. Other effects that may occur are watery or severe diarrhoea which may also be bloody; signs of frequent infections with fever, severe chills, sore throat or mouth ulcers; severe blisters and bleeding in the lips, eye, mouth, nose or genitals; tingling or numbness of hands or feet, pins and needles or muscle weakness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

#### METRONIDAZOLE NORIDEM

• Active ingredient(s): Metronidazole

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using METRONIDAZOLE NORIDEM You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using METRONIDAZOLE NORIDEM

#### Where to find information in this leaflet:

- 1. Why am I being given METRONIDAZOLE NORIDEM?
- 2. What should I know before I am given METRONIDAZOLE NORIDEM?
- 3. What if I am taking other medicines?
- 4. How is METRONIDAZOLE NORIDEM given?
- 5. What should I know while being given METRONIDAZOLE NORIDEM?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I being given METRONIDAZOLE NORIDEM?

METRONIDAZOLE NORIDEM contains the active ingredient Metronidazole.

**METRONIDAZOLE NORIDEM** is used to treat serious infections caused by bacteria and other organisms when metronidazole cannot be given orally. It is also used to prevent certain infections that may occur during surgery.

**METRONIDAZOLE NORIDEM** is an antibiotic which works by killing or stopping the growth of bacteria and other organisms causing these infections.

## 2. What should I know before I am given METRONIDAZOLE NORIDEM?

#### Warnings

#### Do not use METRONIDAZOLE NORIDEM if:

- You are allergic to metronidazole, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives.
- you have or have had a blood disorder
- you have a disease or disorder involving the brain, spinal cord or nerves
- you have taken disulfiram (a medicine used to treat chronic alcohol dependence) within the last two weeks
- you have drunk any alcohol or products containing propylene glycol
- you have Cockayne syndrome

If you are not sure whether you should be given this medicine, talk to your doctor.

#### Check with your doctor if you

- have had any of the following medical conditions:-
  - blood disease or history of blood disease
  - disease or disorder involving the brain, spinal cord or nerves
  - liver disease or any liver problems
  - heart disease or any heart problems
  - any kidney problems
  - Crohn's disease, an inflammatory disease of the intestines
- drink alcohol. Do not drink alcohol during (and for 3 days after stopping) treatment with metronidazole
- if you are on a low sodium diet

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Metronidazole may affect your developing baby if you use it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Metronidazole passes into breast milk and may affect your baby.

If you have not told your doctor about any of the above, tell your doctor before you are given METRONIDAZOLE NORIDEM

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with metronidazole and affect how it works. These include:

- disulfiram, a medicine used to treat chronic alcohol dependence
- some anticancer drugs such as carmustine, cyclophosphamide fluorouracil, 5-fluorouracil and busulfan
- warfarin or other medicines used to prevent blood clots
- phenytoin, a medicine used to treat convulsions
- phenobarbital(phenobarbitone), a medicine to treat convulsions or for sedation
- · cimetidine, a medicine used to treat ulcers
- corticosteroids such as prednisone or cortisone

- lithium, a medicine used to treat some types of depression
- azathioprine, a medicine used to suppress the immune system
- ciclosporin, a medicine used to prevent organ transplant rejection or to treat immune responses
- alcohol, medications containing alcohol (ethanol)
  e.g., some cough syrups, or products containing
  propylene glycol taken with metronidazole can cause
  abdominal cramps, nausea, vomiting, headaches and
  flushing.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect METRONIDAZOLE NORIDEM.

## 4. How is METRONIDAZOLE NORIDEM given?

- Metronidazole Intravenous Infusion is given by injection into a vein.
- Metronidazole Intravenous Infusion must only be given by a doctor or nurse.
- Your doctor will decide what dose and how long you will receive METRONIDAZOLE NORIDEM.
   This will depend on your age, weight, type of infection and how well your kidneys and liver are working.
- The usual adult dose of METRONIDAZOLE NORIDEM is 500mg is given by injection into a vein every eight hours for the course of treatment, as decided by your doctor.
- METRONIDAZOLE NORIDEM must only be given by a doctor or nurse.

#### If you use too much Metronidazole Intravenous Infusion

As METRONIDAZOLE NORIDEM is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much.

If you think that you have been given too much metronidazole, you may need urgent medical attention.

You should immediately: phone the Poisons Information Centre (by calling 13 11 26), contact your doctor, or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while being given METRONIDAZOLE NORIDEM?

#### Things you should do

 If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after METRONIDAZOLE NORIDEM has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

- If the symptoms of your infection do not improve or if they become worse, tell your doctor
- If you get a sore white mouth or tongue while using or soon after stopping METRONIDAZOLE NORIDEM, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.
   This may mean you have a fungal infection called
  - This may mean you have a fungal infection called thrush. Sometimes the use of METRONIDAZOLE NORIDEM allows fungi to grow and the above symptoms to occur. METRONIDAZOLE NORIDEM does not work against fungi.
- If you are using METRONIDAZOLE NORIDEM for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.
- If you need to have any blood tests tell your doctor you are being given METRONIDAZOLE NORIDEM.
   METRONIDAZOLE NORIDEM may affect the results of some blood tests.
- If you become pregnant while you are being treated with METRONIDAZOLE NORIDEM tell your doctor immediately.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given METRONIDAZOLE NORIDEM.

#### Things you should not do

## **Drinking alcohol**

Tell your doctor if you drink alcohol.

 Do not drink any alcohol or any alcoholic drinks while being treated with (and for at least 3 days after stopping) METRONIDAZOLE NORIDEM
 Alcohol with METRONIDAZOLE NORIDEM may make you feel sick, vomit or have stomach cramps, headaches or flushing.

## **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how METRONIDAZOLE NORIDEM affects you.

METRONIDAZOLE NORIDEM may cause dizziness, confusion, hallucination (hearing or seeing strange or unusual things), convulsions ("fits") or affect how you see things.

## Looking after your medicine

 METRONIDAZOLE NORIDEM will be stored in the pharmacy or on the ward. The infusion is kept in a cool dry place, protected from light, where the temperature stays below 30°C.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Les	s serious side effects	What to do		
Gastrointestinal/Digestive				
•	nausea and vomiting	Speak to your doctor		
•	'gas' or abdominal bloating	if you have		
•	loss of appetite	any of these		
•	constipation/diarrhoea	less serious		
•	abdominal pain, indigestion or	side effects		
	discomfort	and they		
Mouth worry you.				
•	metallic or unpleasant taste in the			
	mouth			
•	swollen red or sore tongue			
•	dryness of the mouth			
•	oral thrush - white, furry, sore			
	tongue and/or mouth			
•	sore, red mouth			
•	ulcers or cold sores			
Nas	sal			
•	nasal congestion			
Mu	scles & Joints			
-	joint pains			
Eye •				
	yellowing of the eyes/skin or flushing			
	blurred/ double vision or other			
	eye problems			
Gor	nito-urinary tract			
•	pain when passing urine or			
	passing more urine than normal			
	blood or pus in the urine, darker			
	urine			
	loss of control of your bladder or			
	bowels			
	feeling of pressure around the			
	pelvis			
	sore back passage, sometimes with			
	bleeding or discharge			
	loss of sex drive or painful sex			
	vaginal thrush - sore and itchy			
	vagina and/or discharge			
	dryness of vagina or genitals			
Neurological				
•	dizziness or spinning sensation			
	problems with sleeping			
	, I- U			

#### Serious side effects

Serious side effects	What to do	
fast erratic heartbeats and /or fainting	call your doctor straight away, or go straight	
General Body	to the	
<ul> <li>rash, itchiness, hives</li> <li>swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing</li> <li>tingling or numbness of the hands or feet, pins and needles or muscle weakness</li> <li>severe blisters and bleeding in the lips, eyes, mouth, nose and</li> </ul>	Emergency Department at your nearest hospital if you notice any of these serious side effects.	
genitals		
<ul> <li>signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul>		
Gastrointestinal		
severe abdominal cramps or		
stomach cramps		
<ul> <li>watery, severe diarrhoea, which</li> </ul>		
may also be bloody		
Ears		
<ul> <li>ringing/persistent noise in the ears (tinnitus) or other hearing problems</li> </ul>		
Injection Site		
<ul> <li>swelling or redness along the vein which is extremely tender when touched</li> </ul>		
Neurological		
<ul> <li>confusion, irritability,</li> </ul>		
depression, disorientation		
<ul> <li>clumsiness, lack of co- ordination, problems with moving or balancing</li> </ul>		
difficulty in speaking		
headache, stiff neck and     extreme sensitivity to bright     light		
iigiit		

# Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (changes in the liver, levels of blood cells or changes in heart rhythm) can only be found when your doctor does tests from time to time to check your progress.

## **Reporting side effects**

fits or seizures

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

#### What METRONIDAZOLE NORIDEM contains

Active ingredient (main ingredient)	Metronidazole	
Other ingredients	<ul> <li>Citric acid monohydrate</li> <li>Dibasic sodium phosphate</li></ul>	
(inactive ingredients)	dodecahydrate <li>Sodium chloride</li> <li>Water for Injections</li>	

## Do not take this medicine if you are allergic to any of these ingredients.

METRONIDAZOLE NORIDEM does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

#### What METRONIDAZOLE NORIDEM looks like

METRONIDAZOLE NORIDEM is a clear, almost colourless to pale yellow solution. It is available in a polypropylene bottle for infusion.

METRONIDAZOLE NORIDEM 500 mg/100 mL

AUST R 384574

METRONIDAZOLE NORIDEM is available in 100 mL bottles in packs of 20 bottles per carton.

## Who distributes METRONIDAZOLE NORIDEM

InterPharma Pty Ltd Suite 103, 39 East Esplanade MANLY NSW 2095 AUSTRALIA

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