

METRONIDAZOLE Tablets 200mg & 400mg

Please read all of this leaflet carefully before you start taking this medicine.

Keep the leaflet; you may need to read it again. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Metronidazole Tablets are and what they are used for

Metronidazole belongs to a group of drugs known as antimicrobials. These are used for bacterial and protozoal infections.

This medicine is used to treat septicaemia (micro-organisms in the body), bacteraemia (bacteria in the blood stream), infection affecting the brain, pelvis and bone; and infection following childbirth. It is used to treat or prevent bacterial infection after surgery. It is also used for infection of the sex organs in both male and female, dysentery (watery stools containing blood and mucus), liver infection, to remove cysts, diarrhoea caused by parasite (Giardia Lamblia), and dental infection, including redness and swelling of the gums.

2. Before you take Metronidazole Tablets

Do not take these tablets if:

- you are allergic to Metronidazole, nitroimidazoles (e.g. tinidazole) or any of the ingredients (see section 6).

Check with your doctor before taking these tablets if:

- you have liver or kidney disease. Your doctor may want to see you regularly to check your blood and urine concentration of Metronidazole
- you have a disease of the nervous system
- you are pregnant, think you may be pregnant or are breast-feeding.

Taking other medicines

Check with your doctor or pharmacist before taking these tablets if you are taking other medicines, including any that you can buy without a prescription. This is especially important if you are being treated with:

- medicines used for thinning blood e.g. warfarin
- phenobarbital or phenytoin – used for epilepsy
- busulfan for leukaemia
- disulfiram for alcoholism.
- lithium for mental illness
- ciclosporin to prevent organ rejection after transplant
- 5-fluorouracil for cancer

Other special warnings

Tests: Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

Alcohol: Do not take this medicine with alcohol or drink alcohol until 48 hours after finishing taking this medicine.

Driving and using machinery

This medicine may make you feel sleepy, dizzy, confused, see or hear things that are not there, give you blurred or double vision or have fits. If this happens do not drive or operate machinery.

Important information about some of the ingredients of Metronidazole Tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The 400mg tablet also contains sunset yellow (E110). This may cause allergic reactions.

3. How to take Metronidazole Tablets

Swallow the tablets whole with a drink of water. Do not crush or chew them. Take them during or after a meal.

Your doctor will decide the dose that is best for you. The pharmacist's label will tell you how many tablets to take and how often. If you are not sure about anything ask your doctor or pharmacist.

It is important to take the medicine for the entire length of time for which it is prescribed otherwise your infection could come back.

DOSES:

For prevention of infections after surgery:

Adults and children over 12 years: 400mg – 8 hourly prior to surgery, not more than 24 hours before operation.

Children under 12 years: Your doctor will decide how much your child should take as this depends on the body weight of the child. To be given 1-2 hours before surgery.

For the treatment of anaerobic bacterial infections:

Adults and children over 12 years: 800mg followed by 400mg 3 times daily

Children under 12 years: Your doctor will decide how much your child should take as this depends on the body weight of the child.

For other types of infections the usual doses are provided in the table below and on the following page:

	Adults and children over 10 years	Children		
		7-10 years	3-7 years	1-3 years
Infection of the sex organs	200mg 3 times daily for 7 days or 400mg twice daily for 5-7 days or 2g as a single dose	Your doctor will decide how much your child should take as this depends on the body weight of the child.		

	Adults and children over 10 years	Children		
		7-10 years	3-7 years	1-3 years
Diarrhoea	2.0g once daily for 3 days or 400mg three times daily for 5 days or 500mg twice daily for 7-10 days	1.0g once daily for 3 days	600-800mg once daily for 3 days	500mg once daily for 3 days
Redness and swelling of gums	200mg 3 times daily for 3 days	100mg 3 times daily for 3 days	100mg twice daily for 3 days	50mg 3 times daily for 3 days
Acute dental infections	200mg 3 times daily for up to 7 days	-	-	-
For all other infections (except preventative)	400mg - 800mg 3 times daily for 5-10 days	200mg - 400mg 3 times daily for 5-10 days	100mg – 200mg 4 times daily for 5-10 days	100mg – 200mg 3 times daily for 5-10 days

If you forget to take a dose:

If you miss a dose of this medicine, take it as soon as possible. However if it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule. DO NOT DOUBLE THE DOSES

If you have taken too many tablets:

If you think you have taken too many tablets, contact your doctor straight away or go to the nearest hospital casualty department. Take with you any remaining tablets and the container so that the medicine can be identified.

4. Possible side effects

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional. Also you can help to make sure medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.mhra.gov.uk/yellowcard alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday - Friday) or fill in a paper form available from your local pharmacy.

If any of the following occur STOP TAKING the tablets IMMEDIATELY and see your doctor or go to a hospital straight away:

- swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing, or you notice an itchy, lumpy rash (hives) or nettle rash (urticaria) - these may mean you are having an allergic reaction to Metronidazole
- fever, stiff neck, headache, see or hear things that aren't there, problems using your arms and legs, problems with speaking or feel confused. These may be symptoms of a serious but very rare side effect affecting the brain (encephalopathy).

Talk to your doctor straight away if you notice any of the following side effects:

- yellowing of the skin and eyes or pale stools; these could be signs of a liver problem
- unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness; these may be signs of a blood disorder
- severe stomach pain which may reach through to your back (pancreatitis).

Tell your doctor or pharmacist if you notice any of the following side effects:

Very rare effects (may happen to less than 1 in 10,000 people):

- fits (convulsions)
- mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- problems with your eyesight such as blurred or double vision
- skin rash, itching or swelling
- headache
- darkening/reddening of the urine
- feeling sleepy or dizzy
- joint or muscle pain.

Frequency not known (cannot be estimated from the available data):

- numbness, tingling, pain, or a feeling of weakness in the arms or legs (may occur following prolonged and/or intensive treatment)
- unpleasant taste in the mouth
- furred tongue
- feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- loss of appetite
- fever
- feeling depressed
- fever, headache, stiff neck and back, feeling sick, skin rash, eyes being very sensitive to bright light (these may be signs of aseptic meningitis)
- loss of vision, decrease in colour vision, pain in the eyes.

5. How to store Metronidazole Tablets

Do not store above 25°C. KEEP THIS MEDICINE IN THE PACK PROVIDED.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

Do not take the tablets if the expiry date on the pack has passed. If you have any medicines that are out of date, return them to your pharmacist for safe disposal.

6. Further information

Ingredients:

Metronidazole Tablets contain either 200mg or 400mg of Metronidazole as the active ingredient. They also contain the following other ingredients: lactose, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

The 200mg tablet also contains maize starch.

The 400mg tablet also contains a dispersed yellow lake containing quinoline yellow (E104) and sunset yellow (E110).

What the medicine looks like:

Metronidazole Tablets 200mg are white convex tablets with the company logo engraved one side and B065 engraved on the other. Metronidazole Tablets 400mg are yellow convex tablets with the company logo engraved one side and 'A' breakline '321' on the other.

This medicine is available in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 56 and 84 tablets. (Not all pack sizes may be marketed).

Who makes this medicine and holds the Product Licence:

Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hants, RG25 3ED

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