

Patient Information Leaflet

METRONIDAZOLE 200MG TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET

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1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of this medicine is Metronidazole 200mg tablets (called Metronidazole tablets in this leaflet). Metronidazole belongs to a group of medicines called antibiotics.

It works by killing bacteria and parasites that cause infections in your body. It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area, stomach and intestines.
- Treat gum ulcers and other dental infections.
- Treat infected leg ulcers and pressure sores.
- Prevent infections after surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE

Do not take Metronidazole tablets and tell your doctor if

You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients (see section 6). Signs of an allergic reaction include a rash, itching, difficulty breathing or swallowing, swelling of the face, tongue or throat.

Warnings and precautions

Talk to your doctor or pharmacist before taking Metronidazole if

- You suffer or have ever suffered from liver problems
- You have kidney problems and are having dialysis (see section 3: 'People having kidney dialysis').
- You suffer from a condition called porphyria (a blood disorder leading to abnormal sensitivity to sunlight and other problems)
- You have a disease of the nervous system
- You have intolerance to some sugars as this medicine contains lactose
- You have been prescribed this medicine for more than 10 days – your doctor may wish to carry out some tests and monitor you closely for development of side effects to your nervous system
- You are affected by Cockayne syndrome. Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with product containing metronidazole. If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with metronidazole and afterwards.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of Metronidazole.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk, and upper extremities.

The highest risk for occurrence of serious skin reactions is within one week, typically, within 48 hours after start of treatment. If you develop a serious rash or another of these skin symptoms, stop taking metronidazole and contact your doctor or seek medical attention immediately.

Tell your doctor immediately and stop taking metronidazole if you develop:

- Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine. Do this even if they have applied to you in the past.

Other medicines and metronidazole

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription such as herbal medicines, especially:

- Medicines to stop your blood clotting (e.g. coumarins, warfarin).
- Medicines used to treat epilepsy (e.g. phenobarbital, phenytoin, primidone). Lithium (used to treat depression).
- Medicines used to treat cancer (e.g. busulfan, fluorouracil or mycophenolate).
- Disulfiram (used to treat alcohol addiction).
- Medicines used to treat stomach ulcers (e.g. cimetidine).
- Oestrogen contraceptives (known as 'the pill').
- Ciclosporin (used to prevent the rejection of organs after transplant).

Metronidazole tablets with food and drink

Do not drink any alcohol while you are taking Metronidazole tablets and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole tablets might cause unpleasant side effects such as nausea (feeling sick), vomiting (being sick), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

Pregnancy and breast-feeding

Speak to your doctor or pharmacist before taking this medicine if:

- you are pregnant, think you may be pregnant or are planning to become pregnant. Metronidazole tablets should not be taken during pregnancy unless considered absolutely necessary.
- you are breast-feeding. It is better not to take this medicine if you are breast-feeding because small amounts of it may pass into the mother's milk.

Always ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine may make you feel drowsy, dizzy, confused or affect your vision, cause fits or hallucinations. Make sure you are not affected before you drive or operate machinery.

Metronidazole tablets contain lactose

This medicine contains a sugar called lactose. Some people may be intolerant to this sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE YOUR MEDICINE

Take this medicine exactly as your doctor has told you. It is important to finish a full course of treatment. The dose and length of your treatment with Metronidazole tablets will depend on your needs and the type of illness being treated. Check with your doctor or pharmacist if you are not sure.

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

The usual dose for adults and children is given below:

To treat bacterial infection:

Adults

- The initial dose is 800mg (4 tablets).
- After 8 hours take another dose of 400mg (2 tablets) and repeat this dose every 8 hours.

Children

- Your doctor will work out how much your child should take depending on their weight.
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

To prevent infections from happening after surgery:

Adults

- Start taking Metronidazole tablets 24 hours before your operation.
- Take 400mg (2 tablets) of Metronidazole tablets every 8 hours.
- After the operation you may be given metronidazole either through a drip into a vein or rectally as a suppository until you are able to take tablets again

Children

- Start giving your child Metronidazole tablets 1-2 hours before their operation. Your doctor will work out how much your child should take depending on their weight.
- After the operation your child may be given metronidazole either through a drip into a vein or rectally as a suppository until they are able to take tablets again

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Other types of infections

For treatment of other infections caused by parasites and some bacteria your doctor will decide how many Metronidazole tablets you need to take and how often. This will depend on your illness and how bad it is. Always check with your doctor or pharmacist if you are not sure.

Elderly

Metronidazole tablets are well tolerated by the elderly but caution should be exercised with high dosage regimens.

People having kidney dialysis

Kidney dialysis removes metronidazole from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

If you take more tablets than you should

If you take more tablets than you should, or if you think a child has accidentally swallowed some tablets, contact the nearest hospital casualty department or speak to your doctor for advice immediately. Take this leaflet and any tablets that you still have, to show the doctor. Signs of an overdose include feeling or being sick, loss of appetite, diarrhoea, metallic taste, headache, dizziness, insomnia or drowsiness.

If you forget to take your tablets

Take the next dose as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten doses.

If you stop taking the tablets

Keep taking the tablets until you have finished the course. Do not stop taking them even if you start to feel better after a few days. If you are unsure about anything, talk to your doctor and follow their advice.

The dose your doctor or pharmacist advises may be different to the doses given in this leaflet. Always follow your doctor or pharmacist's instructions when taking any medicines.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Metronidazole tablets can cause side effects, although not everybody gets them.

Stop taking your medicine and see a doctor or go to a hospital immediately if:

- You have an allergic reaction (signs include skin rash, flaking skin, boils, sore lips or mouth; wheezing; fluttering or tightness of the chest or collapse; swelling of the face, tongue or throat).
- You suffer a serious but very rare brain disease (encephalopathy). Symptoms may include a fever, stiff neck, headache, hallucinations, problems using your arms and legs, problems with speaking, feeling confused.
- You develop skin rashes with blistering, peeling or bleeding of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of severe allergic skin reactions called Stevens - Johnson syndrome or toxic epidermal necrolysis.
- You develop a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately.

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

- Blood disorders (signs may include increased bruising, sore throats, unexpected infections, mouth ulcers, bleeding gums or unusual tiredness)
- Yellowing skin and whites of the eyes
- 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 (affects less than 1 in 10 000 people)

- Fits (convulsions)
- Feelings of confusion, seeing or hearing things that are not there (hallucinations)
- Muscle weakness, muscle pain or joint pain
- Eyesight problems such as blurred or double vision
- Drowsiness, dizziness, headaches
- Skin rashes, itching, blisters, circular red patches on the skin. Darkening of urine
- Liver problems including life-threatening liver failure (hepatocellular liver injury)
- Abnormal liver function tests

Not known (frequency cannot be estimated from the available data)

- Paralysis (numbness), tingling, pain or a feeling of weakness in the arms or legs
- Unpleasant taste in the mouth. Furred tongue
- Feeling sick, being sick, upset stomach or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed
- Pain in your eyes (optic neuritis)
- Hearing impairment/hearing loss
- Ringing in the ears (tinnitus)
- A group of symptoms together including fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)
- You get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play and Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YOUR MEDICINE

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the label.

Store in dry place, below 25°C.

Keep container tightly closed, protect from light.

Do not use if you notice any damage or discolouration to the tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Metronidazole tablets contain

The active substance is metronidazole. Each tablet contains 200mg of metronidazole.

The other ingredients are lactose, maize starch, pregelatinised maize starch, sodium starch glycolate and magnesium stearate.

What Metronidazole tablets look like and contents of the pack

Metronidazole tablets are flat, white or creamy-white scored tablets.

These tablets are available in blister packs of 21 tablets and container packs of 21, 28, 56 and 250 tablets (not all pack sizes are marketed).

Marketing Authorisation Holder and Manufacturer:

Intrapharm Laboratories Limited,
The Courtyard Barns,
Choke Lane,
Cookham Dean,
Maidenhead,
Berkshire,
SL6 6PT,
UNITED KINGDOM.

For any information about this medicine, please contact the Marketing Authorisation Holder on the details provided above.

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Other formats

To request a copy of this leaflet in Braille, large print or audio, please call +880 1628 771800.

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