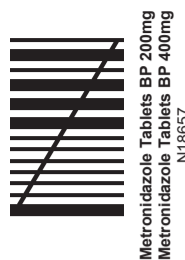


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PACKAGE LEAFLET: INFORMATION FOR THE USER

Metronidazole Tablets BP 200mg Metronidazole Tablets BP 400mg metronidazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

What is in this leaflet:

1. What Metronidazole Tablets are and what they are used for
2. What you need to know before you take Metronidazole Tablets
3. How to take Metronidazole Tablets
4. Possible side effects
5. How to store Metronidazole Tablets
6. Contents of the pack and other information

1. WHAT METRONIDAZOLE TABLETS ARE AND WHAT THEY ARE USED FOR

The name of this medicine is metronidazole. This 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

If you need any further information on your illness, speak to your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METRONIDAZOLE TABLETS

Do not take Metronidazole Tablets if:

- You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients of this medicine (listed in Section 6).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Do not take Metronidazole if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Metronidazole.

Warnings and precautions

Talk to your doctor or pharmacist before taking Metronidazole Tablets if:

- You have or have ever had a liver problem
- You are having kidney dialysis (see section 3: 'People having kidney dialysis').
- You have a disease of the nervous system

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

Tell your doctor immediately and stop taking metronidazole if you develop: stomach pain, anorexia (loss of appetite), nausea (feeling sick), vomiting (being sick), fever, malaise, fatigue, vertigo (spinning sensation), jaundice, dark urine, putty or mastic-coloured stools or itching.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with 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.**

Other medicines and Metronidazole Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Metronidazole can affect the way some other medicines work. Also, some other medicines can affect the way Metronidazole works.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy
- 5-fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin to prevent the rejection of organs after transplant
- Disulfiram for alcoholism
- Medicines that may cause heart rhythm disturbances (so-called QT prolongation which can be seen on ECG) such as:
 - certain anti-arrhythmics (medicines for heart rhythm disorders)
 - certain antibiotics
 - medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought)

If you are not sure, talk to your doctor or pharmacist before taking metronidazole.

Metronidazole Tablets with alcohol

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

Pregnancy and breast-feeding

Tell your doctor before taking Metronidazole if:

- You are pregnant, might become pregnant or think you may be pregnant. Metronidazole should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to use Metronidazole if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

While taking Metronidazole you may feel dizzy or experience vertigo (spinning sensation), confusion, hallucinations (seeing or hearing things that are not there), convulsions (fits) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

Tests

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days. If you are going to have a blood test, tell the doctor or nurse performing the test that you are using metronidazole. Metronidazole can affect the results of some blood tests.

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

3. HOW TO TAKE METRONIDAZOLE TABLETS

Taking your medicine

Always take metronidazole exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important to finish a full course of treatment. The length of a course will depend on your needs and the 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 dose of metronidazole will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is.

The recommended dose is:

To treat bacterial infection

Adults

- The initial dose is 800mg
- After 8 hours take another dose of 400mg 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 400 mg of metronidazole 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

Other types of infections

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much metronidazole you need to take and how often. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you how many tablets to take and how often to take them.

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.

People with liver problems

Your doctor may tell you to use a lower dose or to use the medicine less often.

If you take more Metronidazole Tablets than you should

If you take more metronidazole than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the pack and any tablets left with you. This is so the doctor knows what you have taken.

If you forget to take Metronidazole Tablets

If you forget to take metronidazole, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Metronidazole Tablets

You should only stop taking metronidazole if your doctor tells you to. It is essential to take the medicine and not to stop and start as this could cause unwanted side effects.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Metronidazole and see a doctor or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- You have an **allergic reaction**. The signs may include: swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing, an itchy, lumpy rash (hives) or nettle rash (urticaria).
- A serious but very rare side effect is a brain disease (encephalopathy). Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feel confused.
- You develop skin rashes including Stevens-Johnson syndrome or toxic epidermal necrolysis. These can appear as reddish target-like spots or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
- 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. See also section 2.
- Yellowing of the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- Severe stomach pain which may reach through to your back (pancreatitis)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

Very rare (affects 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 or flushing
- Headache

- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life threatening liver failure (hepatocellular liver injury)

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

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- 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
- Pain in your eyes (optic neuritis)
- 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)
- Hearing impairment/ hearing loss
- Ringing in the ears (tinnitus)
- Vertigo (spinning sensation)
- 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
- Acute liver failure in patients with Cockayne Syndrome (see section 2 "Warnings and precautions")
- Heart rhythm disturbances (so-called QT prolongation which can be seen on ECG), particularly when metronidazole is used with other medicines that may cause heart rhythm disturbances

Reporting of side effects

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

5. HOW TO STORE METRONIDAZOLE TABLETS

- Keep this medicine out of the sight and reach of children.
- Store below 25°C in original packing.
- Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Metronidazole Tablets contain

Each tablet contains 200mg or 400mg of metronidazole as the active substance.

The other ingredients are povidone, magnesium stearate, colloidal anhydrous silica and maize starch.

What Metronidazole Tablets look like and contents of the pack

The tablets are off-white coloured, round, biconvex and uncoated, engraved with either 'MZ 200' (200mg) or 'MZ 400' (400mg) and a break line on one side whilst plain on the other.

Metronidazole Tablets 200mg are available in containers of 7, 14, 15, 21, 28, 42, 56, 70, 84, 100, 250, 500 and 1000 as well as in bottles containing 50 tablets.

Metronidazole Tablets 400mg are available in containers of 28, 30, 50, 60, 84, 90, 100, 112, 120, 140, 168, 180, 500 and 1000 tablets.

They are also available in blister packs of 7, 14, 15, 21, 28, 42, 56, 70 and 84 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Milpharm Limited,
Ares, Odyssey Business Park, West End Road, South Ruislip, HA4 6QD
United Kingdom

Manufacturers:

Milpharm Limited,
Ares, Odyssey Business Park, West End Road, South Ruislip, HA4 6QD
United Kingdom

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This leaflet was last revised in 03/2024.