

METRONIDAZOLE 200 mg AND 400 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Metronidazole is and what it is used for
2. Before you take Metronidazole
3. How to take Metronidazole
4. Possible side effects
5. How to store Metronidazole
6. Further information

1 WHAT METRONIDAZOLE IS AND WHAT IT IS USED FOR

Your tablets are called Metronidazole Tablets. They are part of a group of drugs known as antimicrobial agents. They kill bacteria and protozoa (single-celled organisms which can cause disease).

Metronidazole Tablets are used to prevent and treat a variety of infections caused by a range of bacteria and protozoa:

- prevention of bacterial infections after surgery and the treatment of infected wounds after surgery
- treatment of susceptible bacterial infections such as infections of the blood, abdomen, lung, bones, pelvic area, brain or wound infections after a surgical operation
- treatment of certain bacterial and protozoal infections of the genital tract
- treatment of infections of the intestinal tract caused by parasitic micro-organisms
- treatment of infected pressure sores and leg ulcers
- treatment of dental infections and ulceration of the gums.

2 BEFORE YOU TAKE METRONIDAZOLE

DO NOT take Metronidazole and contact your doctor if you:

- are **allergic** (hypersensitive) to metronidazole or any of the other ingredients of this medicine, see section 6 for the full list of ingredients.

Take special care with Metronidazole

Tell your doctor before you start to take this medicine if you:

- have a disease which is affecting your brain, nervous system or spinal cord
- have an intolerance to some sugars, e.g. lactose
- have ever had or currently have any problems with your liver.

Taking other medicines

Talk to your doctor if you are taking any of the following:

- **blood thinning tablets** (anticoagulants e.g. warfarin), as metronidazole may increase their effect. If your doctor thinks you need both medicines, it may be necessary to reduce the dose of the anticoagulant and/or increase the frequency of your blood checks
- **lithium** (used for depression and other severe behavioural disorders), as metronidazole may increase its effect. Your doctor may reduce your lithium dose and should monitor your blood levels and kidney function more frequently than normal
- **treatment for epilepsy**, particularly phenytoin and/or barbiturates such as phenobarbital, as their effectiveness may be altered if used with metronidazole
- **medicines for the treatment of cancer**, as taking metronidazole in combination with some of these (particularly fluorouracil or busulfan) may increase their adverse effects
- **ciclosporin** (used to suppress the immune system), as metronidazole may increase its effect. If your doctor thinks you need both medicines, blood levels and kidney function should be monitored more frequently than normal
- **cimetidine** (used to control the effects of excess stomach acid such as ulcers and heartburn), as this may possibly increase the unwanted effects of metronidazole
- **"the pill" (oral contraceptive)**, as metronidazole may reduce its effectiveness
- **disulfiram** (Antabuse – used for chronic alcohol dependence), as metronidazole may increase the risk of developing severe behavioural reactions.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Other important things to remember while taking this medicine:

- In patients undergoing haemodialysis Metronidazole and metabolites are efficiently removed during an eight-hour period of dialysis. Metronidazole should therefore be re-administered immediately after haemodialysis.
- If you are to take Metronidazole Tablets for more than 10 days, you may need to have regular blood tests.
- If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.

Important information about some of the ingredients of Metronidazole

- Patients who are intolerant to **lactose** should note that Metronidazole tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking Metronidazole with food and drink

- **DO NOT drink alcohol** while you are taking Metronidazole Tablets or you may experience vomiting, flushing, headaches, palpitations or breathing difficulties.

Pregnancy and breast-feeding

- If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines

- Metronidazole may cause dizziness, drowsiness, you may feel confused, have hallucinations or convulsions or your eye-sight may be affected. If you are affected, **DO NOT drive** or operate machinery or take part in activities where such effects may put you or others at risk.

Pharma code

Pharma code

3 HOW TO TAKE METRONIDAZOLE

Always take Metronidazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water. They should not be chewed. It is recommended that the tablets be taken during or after a meal.

The following is a guide to the doses.

Infection	Dose				Length of Treatment
	Adults and children over 10 years	Children			
		Age 7 to 10 years	Age 3 to 7 years	Age 1 to 3 years	
Anaerobic infections (e.g. blood poisoning, pneumonia, pelvis abscess)	800 mg initially and 400 mg three times a day	7.5 mg/kg three times a day for three days and then twice a day	7.5 mg/kg three times a day for three days and then twice a day	Not suitable	Usually 7 days
Prevention of anaerobic infections	400 mg every eight hours during the 24 hours before an operation.	7.5 mg/kg every eight hours	Not suitable		N/A
Inflammation of the vagina	400 mg twice a day or 2 g as a single dose	Not suitable			7 days 1 day

Infection	Dose				Length of Treatment
	Adults and children over 10 years	Children			
		Age 7 to 10 years	Age 3 to 7 years	Age 1 to 3 years	
Trichomoniasis (infection of the urogenital tract and in adults the partner should receive similar treatment)	200 mg three times a day	100 mg three times a day	100 mg twice a day	Not suitable	7 days
	800 mg in the morning and 1.2 g at night				2 days
	2 g as a single dose or in 2 divided doses				1 day
Giardiasis (infection in the small intestine)	2 g once a day	1 g once a day	600 mg once a day	400 mg to 500 mg once a day	3 days
Amoebiasis (infection of the intestinal tract)	400 mg to 800 mg three times a day	200 mg to 400 mg three times a day	100 mg to 200 mg four times a day	100 mg to 200 mg three times a day	5-10 days
Inflammation of the gums	200 mg three times a day	100 mg three times a day	100 mg twice a day	Not suitable	3 days
Dental infections	200 mg three times a day or 400 mg three times daily	Not suitable	Not suitable	Not suitable	3 to 7 days
Leg ulcers and pressure sores	400 mg three times a day	Not suitable			7 days
Pelvic infections	400 mg twice a day	Not suitable			14 days

If you take more Metronidazole than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause severe gastro-intestinal disturbances, vomiting, difficulty in controlling movements and slight disorientation.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Metronidazole

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

If you stop taking Metronidazole

DO NOT stop taking your medicine without talking to your doctor first even if you feel better.

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 can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or nettle rash).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

There may be a reduction (sometimes severe) in normal blood cells. If you develop any of the following **tell your doctor immediately**.

- unexplained bruising or bleeding
- increased frequency of or persistent infections especially sore throat
- skin pallor particularly if you also have weakness and/or breathlessness
- increased frequency of severe mouth ulcers.

The following side effects have also been reported:

- blistering of the skin, mouth, eyes and genitals that can be severe
- stomach pain or upset, feeling sick, diarrhoea, sore mouth, unpleasant taste, dry mouth, furred tongue, and loss of appetite. Very occasional inflammation of the pancreas, indicated by severe pain in the abdomen and back, may occur
- effects on your nervous system have been reported very rarely which may include drowsiness, dizziness, headache, speech difficulties, difficulty in walking or poor co-ordination, shaking, seeing hearing or feeling things that are not there, confusion, double vision, short sightedness. Consult your doctor if you suffer an epileptic-type fit or notice that you have feelings of numbness, tingling, burning, pain or a feeling of weakness in the arms or legs
- liver problems, hepatitis or jaundice (where your skin and the whites of your eyes go slightly yellow)
- darkening of urine.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE METRONIDAZOLE

Keep out of the reach and sight of children.

Store in a cool, dry place and protect from light. Store in the original package.

Do not use Metronidazole after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

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 FURTHER INFORMATION

What Metronidazole Tablets contain:

- The active ingredient is metronidazole 200 mg or 400 mg
- The other ingredients are lactose, maize starch, pregelatinised starch, polyvidone, colloidal silicon dioxide and magnesium stearate.

What Metronidazole Tablets look like and contents of the pack:

- Metronidazole 200 mg Tablets are white biconvex tablets coded MZL 200 with a breakline on one side, twin triangle logo on the reverse.
 - Metronidazole 400 mg Tablets are white biconvex tablets coded MZL 400 with a breakline on one side, twin triangle logo on the reverse.
 - The 200 mg tablets are available in packs of 7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 60, 250, 500, 1000, 5,000 and 10,000.
 - The 400 mg tablets are available in packs of 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 100, 250, 500 and 1000.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG.

Company responsible for manufacture: Teva Pharmaceutical Works Private Limited Company, H2100 Gödöllo, Táncsics Mihály út 82, Budapest, Hungary.

This leaflet was last revised: October 2010

PL 00289/1596-7

Pharma code

Pharma code

HP6012