

Package leaflet: Information for the user

Metronidazole 500 mg Film Coated Tablets

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, please 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 is and what it is used for
2. What you need to know before you take Metronidazole
3. How to take Metronidazole
4. Possible side effects
5. How to store Metronidazole
6. Contents of the pack and other information

1. What Metronidazole is and what it is used for

Metronidazole is an anti-infective medicine. It is effective against a wide range of micro-organisms. It is used to treat the following:

- Ulcers in the stomach caused by a type of bacteria called *Helicobacter pylori*
- Genital or urinary tract infections caused by a parasite called *Trichomonas*
- Infections of the gums and/or teeth
- Bacterial infection of the genitals in females
- Bacterial infections in: the blood, the brain, the bones, the lungs, the stomach lining, the pelvic area after childbirth, a wound after an operation
- A parasitic disease called *Giardiasis*
- A parasitic disease called *Amoebiasis*
- Infected leg ulcers or bedsores

Metronidazole can also be used to prevent infections following an operation.

2. What you need to know before you take Metronidazole

Do not take Metronidazole if you:

- are allergic to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients of this medicine (listed in section 6)
- are in the first trimester (first three months) of your pregnancy
- are breast-feeding

Warnings and precautions

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

- have kidney disease, especially if you are receiving dialysis treatments
- have ever had liver disease
- are in the second or third trimester (4th – 9th month) of your pregnancy
- have ever suffered from ‘fits’ or if you have been diagnosed with epilepsy
- have a genetic disease called porphyria, which can cause: skin blisters, brain disorders, nervous system disorders and abdominal pain
- have a blood disorder or disorder of any blood cells
- may have been exposed to a sexually transmitted disease
- have a nervous system disorder

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 products 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 Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of Metronidazole 500 mg Film Coated Tablets.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blister 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 of 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

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Speak with your doctor if you are taking any of the following medications:

- medicines used to prevent blood clotting such as warfarin
 - medicines used to treat epilepsy such as phenytoin, phenobarbital & primidone
 - disulfiram, a medicine to treat alcohol addiction
 - lithium for mental illness, a medicine to treat depression
 - ciclosporin, a medicine used following organ transplant
 - fluorouracil, a medicine used to treat some forms of cancer
 - busulfan, a medicine used to treat leukaemia (cancer of the blood cells)
 - cimetidine, a medicine used to treat stomach ulcers
 - oral contraceptive medicines containing oestrogen
- If you are not sure, talk to your doctor or pharmacist before taking Metronidazole.

Metronidazole with food, drink and alcohol

You should not consume alcohol whilst taking and 48 hours after finishing your course of Metronidazole. 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

Metronidazole must not be taken in the first trimester of pregnancy. Metronidazole should not be used in the second and third trimester of pregnancy.

If you are breast-feeding, you should stop whilst you are taking Metronidazole and for 24 hours after the course of tablets has finished. This is because small amounts may pass into the mother’s milk.

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 this medicine.

Driving and using machines

While using 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). You should make sure you do not drive, operate machinery or take part in any activities that could put you or others at risk until you know how Metronidazole affects you.

Metronidazole tablets contain wheat starch

This medicine contains only very low levels of gluten (from wheat starch) and is unlikely to cause problems if you have coeliac disease.

One 500mg tablet contains no more than 164.30 micrograms of gluten.

If you have a wheat allergy (different from coeliac disease) you should not take this medicine.

Tests

If you are taking this medicine for more than 10 days, your doctor may wish to carry out further tests. If you need any blood or urine tests, tell your doctor you are taking Metronidazole tablets before the test.

3. How to take Metronidazole

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important to finish a full course of treatment.

Metronidazole should be taken during or after meals. Swallow the tablets whole, do not crush or chew them.

The recommended dose and length of a course will vary depending on the condition being treated. Metronidazole should be taken exactly as directed by your doctor.

For doses less than 500 mg (one tablet) an alternative dosage form should be used.

If you are elderly or have liver disease, this may affect the dosage your doctor prescribes.

To treat anaerobic infections

Treatment for 7 days should be satisfactory for most patients but, depending upon clinical and bacteriological assessments, the physician may decide to prolong treatment.

- Children aged 8 weeks to 12 years: 20-30 mg/kg/day as a single dose or divided into 7.5 mg/kg every 8 hours. The daily dose may be increased to 40 mg/kg, depending on the severity of the infection.
- Children under 8 weeks: 15 mg/kg as a single daily dose or divided into 7.5 mg/kg every 12 hours.
- Children under 10 years: a more suitable dosage form should be used.

To prevent infections after surgery

- Adults: 1000 mg as a single dose 24 hours before surgery followed by 400 mg at 8 hourly intervals during the 24 hours after the operation.
- Children under 12 years: 20-30 mg/kg as a single dose given 1-2 hours before surgery.
- Newborns with gestation age less than 40 weeks: 10 mg/kg body weight as a single dose before the operation.
- Children under 10 years: a more suitable dosage form should be used.

Treatment of established infections

- Adults and children over 10 years: 800 mg followed by 400 mg every 8 hours.
- Children under 10 years: a more suitable dosage form should be used.

To treat infection caused by *Trichomonas*

- Adults and adolescents: 2000 mg as a single dose or 200 mg 3 times a day for 7 days, or 400 mg twice a day for 5-7 days. Your partner should also be treated.

- Children under 10 years: 40 mg/kg taken orally as a single dose or 15-30 mg/kg/day divided into 2-3 doses taken over 7 days. Doses should not exceed 2000 mg/dose.
- Children under 10 years: a more suitable dosage form should be used.

Genital infections in women

- Adults: 400 mg taken twice daily for 7 days, or 2000 mg as a single dose for 1 day only.
- Adolescents: 400 mg taken twice daily for 5-7 days, or 2000 mg as a single dose.

To treat amoebiasis

- Adults and children over 10 years: 400 to 800 mg 3 times a day for 5-10 days.
- Children 7 to 10 years: 200 to 400 mg 3 times a day for 5-10 days.
- Children 3 to 7 years: 100 to 200 mg 4 times a day for 5-10 days.
- Children 1 to 3 years: 100 to 200 mg 3 times a day for 5-10 days, or 35 to 50 mg/kg daily in 3 divided doses for 5-10 days, not exceeding 2400 mg/day.
- Children under 7 years: a more suitable dosage form should be used.

To treat giardiasis

- Adults and children over 10 years: 2000 mg once a day for 3 days, or 400 mg three times a day for 5 days, or 500 mg twice daily for 7-10 days.
- Children 7 to 10 years: 1000 mg once a day for 3 days.
- Children 3 to 7 years: 600 to 800 mg once a day for 3 days.
- Children 1 to 3 years: 500 mg once a day for 3 days, or 15-40 mg/kg/day divided into 2-3 doses.
- Children under 7 years: a more suitable dosage form should be used.

To treat infections of the gums (for 3 days) or teeth (for 3-7 days)

- Adults and children over 10 years: 200 mg 3 times a day.
- Children under 10 years: a more suitable dosage form should be used.

To treat infected leg ulcers and pressure sores (for 7 days)

- Adults and children over 10 years: 400 mg 3 times a day.

To treat stomach ulcers caused by *Helicobacter pylori*

- To be taken as part of a combination therapy as directed by your doctor, 20 mg/kg/day, not exceeding 500 mg twice daily for 7-14 days.

If you take more Metronidazole than you should

If you or someone else may have swallowed a lot of Metronidazole tablets, contact your nearest casualty department or tell your doctor straight away. You should take the package with you even if it is empty. Signs of an overdose include nausea, being sick, loss of appetite, diarrhoea, headache, dizziness, drowsiness, insomnia and metallic taste.

If you forget to take Metronidazole

If you forget to take Metronidazole, do not worry. Take your dose as soon as you remember, unless it is nearly time for your next dose, in which case just continue to take your next dose as normal. Do not take a double dose to make up for a forgotten dose.

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

If you stop taking Metronidazole

If you stop taking Metronidazole tablets your infection may come back. Seek the advice of your doctor before you stop taking Metronidazole tablets.

4. Possible side effects

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Metronidazole.

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, or 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 Flagyl 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 Flagyl 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)

Other Side effects:

Very rare (affects less than 1 in 10,000 people):

- Increased bruising, nosebleeds, sore throats or infections - this medicine may alter the numbers and types of your blood cells. Your doctor may want you to have a blood test if you experience any of these symptoms
- Mental health problems including hallucinations (seeing or hearing things that are not there)
- Drowsiness, dizziness, fits (convulsions), tingling, numbness, pain or a feeling of weakness in the arms or legs
- Encephalopathy (headaches, light sensitivity, confusion, fever, paralysis, a 'stiff neck')
- Cerebellar syndrome (poor muscle control co-ordination, involuntary shaking, uncontrolled eye movements, speech disorders, abnormal walking)
- Double or blurred vision, short sightedness
- Changes in liver function tests, jaundice (yellowing of the skin or whites of the eyes)
- Pancreatitis (inflammation of the pancreas causing very severe abdominal pain)
- Flushing
- Skin rashes, itching, small pus-containing blisters
- Muscle and joint pain
- Darkening of the urine
- Liver problems including life-threatening liver failure (hepatocellular livery injury)

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

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs.
- Acute liver failure in patients with Cockayne Syndrome (see section 2 "Warnings and precautions")
- Bone marrow depression disorders such as aplastic anaemia (causing weakness, bruising and increasing the likelihood of infections)
- Urticaria (itchy, pale or red irregular raised patches of skin)
- Fever
- Depression
- Pain in your eyes (optic neuritis)
- 'Pins and needles'
- An unpleasant taste in the mouth, changes in taste, furred tongue, mouth ulcers
- Feeling or being sick, loss of appetite, diarrhoea, stomach pain and upset stomach
- Erythema multiforme (circular, irregular red patches)
- 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

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 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

Keep blister packs in the outer carton, protected from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metronidazole contains

- The active substance is Metronidazole 500 mg
- The other ingredients are: wheat starch, povidone (K30), magnesium stearate, hypromellose & macrogol (type 20000)

What Metronidazole looks like and contents of the pack

Metronidazole 500 mg Film Coated Tablets are white to yellow, round, biconvex film-coated tablets with 'M2' embossed on one side.

Metronidazole is available in packs of 21 tablets.

Marketing Authorisation Holder

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