

Metronidazole tablets 500mg

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Metronidazole tablets are and what they are used for

Metronidazole tablets belong to a group of medicines called anti-infective agents. They may be used to **treat**:

- infections, caused by bacteria of the blood, brain, bone, lung, stomach lining and pelvic area, following childbirth or in a wound following an operation
- urinary or genital infections caused by a parasite, *Trichomonas*
- genital infection in women caused by bacteria
- the parasitic diseases *amoebiasis*

- the disease *giardiasis*
- gum and teeth infections
- infected leg ulcers or pressure sores
- stomach ulcers caused by *Helicobacter pylori*.
- or **prevent** infections occurring after operations.

2 What you need to know before you take Metronidazole tablets

Do not take Metronidazole tablets:

- if you are **allergic** 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.
- if you are in the **first 3 months of pregnancy** or are **breastfeeding**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Metronidazole tablets:

- if you have **kidney** disease, particularly if you require **dialysis** treatments
- if you have ever suffered from any **liver** disease
- if you are in the **4th-9th month of pregnancy**
- if you have **epilepsy** or have ever had **fits**
- if you have **porphyria** (a genetic disease that can cause skin blisters, abdominal pain and brain/nervous system disorders)
- if you have any disorder of the **blood** and/or **blood cells**
- if you have any **nervous system** disorders
- if you have been exposed to any **sexually transmitted disease**.

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.

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.

Other medicines and Metronidazole tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription and herbal medicines. This is because Metronidazole tablets can affect the way some other medicines work. Also, some other medicines can affect the way Metronidazole tablets work. Especially:

- medicines to stop the blood clotting such as warfarin
- lithium (used to treat depression)
- medicines to treat epilepsy such as phenobarbital, phenytoin, primidone
- disulfiram (to treat alcohol addiction)
- ciclosporin (used following organ transplants)
- fluorouracil (used to treat some forms of cancer)
- busulfan for leukaemia (cancer of the blood cells)
- cimetidine (used to treat stomach ulcers)
- oestrogen contraceptives ('the pill').

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

Metronidazole tablets with food, drink and alcohol

You are advised **not to drink alcohol whilst taking this medicine and for 48 hours after finishing the course of tablets**, as this might cause unpleasant side-effects, such as feeling or being sick, stomach pain, hot flushes, palpitations and headache.

Pregnancy and breastfeeding

Metronidazole tablets **must** not be taken during the first 3 months of pregnancy and **should** not be taken during the rest of the pregnancy. If you breastfeed you should **stop whilst taking Metronidazole tablets and for 12-24 hours after** the course of tablets has finished before breastfeeding again.

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

Driving and using machines

Metronidazole tablets may make you feel drowsy, dizzy, confused or affect your vision, cause fits or hallucinations. Make sure you are not affected

before you drive, operate machinery or take part in any activities where these may put you or others at risk.

Metronidazole tablets contain lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a sugar called lactose.

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 tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **whole, during or after meals**, with a glass of water. **Do not chew them.**

The recommended dose is:

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

To treat bacterial infections

- Adults and children over 10 years: 800mg followed by 400mg at eight hourly intervals. Treatment is usually for 7 days but will depend upon your condition.

To treat anaerobic infections

- Children 8 weeks-12 years: 20-30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours for 7 days. The daily dose may be increased to 40mg/kg, depending on the severity of the infection.
- Children under 8 weeks: 15mg/kg/day as a single dose or divided into 7.5mg/kg every 12 hours.
- Children under 10 years: A more suitable dosage form should be used for this age group.

To treat infection caused by *Trichomonas*

- Adults and adolescents: 2g as a single dose, or 200mg three times a day for 7 days, or 400mg twice a day for 5-7 days. Your partner should also be treated.
- Children under 10 years: 40mg/kg as a single dose or 15-30mg/kg/day two to three times daily for 7 days. Doses should not to exceed 2000mg/dose.
- Children under 10 years: A more suitable dosage form should be used for this age group.

To treat non-specific genital infection in women

- Women: 400mg twice a day for 7 days, or 2g as a single dose for 1 day only.
- Adolescent girls: 400mg twice daily for 5 to 7 days or 2g as a single dose.

To treat *amoebiasis*

- Adults and children over 10 years: 400mg-800mg three times a day for 5 to 10 days.
- Children 7-10 years: 200mg-400mg three times a day for 5 to 10 days.
- Children 3-7 years: 100mg-200mg four times daily for 5 to 10 days.
- Children 1-3 years: 100mg-200mg three times daily for 5 to 10 days. Or 35-50mg/kg/day in 3 divided doses for 5 to 10 days.
- Children under 7 years: A more suitable dosage form should be used for this age group.

To treat *giardiasis*

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

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

- Adults and children over 10 years: 200mg three times a day.

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

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

To treat stomach ulcers caused by *Helicobacter pylori*

To be taken as directed by your doctor as part of a course with two other medicines.

To prevent infections after surgery

- Adults: 1g as a single dose 24 hours before surgery then, 400mg at 8 hourly intervals during the 24 hours before the operation.
- Children under 12 years: 20-30mg/kg as a single dose 1-2 hours before the operation.
- Newborns with a gestation age less than 40 weeks: 10 mg/kg body weight as a single dose before operation.

- Children under 10 years: A more suitable dosage form should be used for this age group.

If you are elderly or have liver disease, it is particularly important to take this medicine exactly as directed by the doctor.

If you take more Metronidazole tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. 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 Metronidazole tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Metronidazole tablets

If you stop taking the tablets your infection may come back.

Talk to your doctor before you stop taking the tablets and follow their advice.

4 Possible side effects

Like all medicines, this medicine can cause side effects, particularly when you first start taking it, although not everybody gets them.

Stop taking Metronidazole tablets and contact your doctor at once if you notice any of the following side effects:

- **allergic reactions:** skin rash, which may be itchy, swelling of the face, lips, tongue or throat, fever or difficulty in breathing.
- symptoms of a severe but rare brain disease (encephalopathy). Symptoms vary but you might get 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 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 something called 'Stevens-Johnson Syndrome' or 'toxic epidermal necrolysis'.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

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

- increased bruising, nosebleeds, sore throats or infections, this medicine may alter the numbers and types of your blood cells. You should tell your doctor who might want you to have a blood test
- mental health problems including confusion, hallucinations (seeing or hearing things that are not there), drowsiness, dizziness, headache, fits, tingling, pain or a feeling of weakness in the arms or legs, numbness
- Cerebellar syndrome (poor co-ordination or muscle control, involuntary shakiness, uncontrolled eye movements, speech disorders, walking abnormally)
- double vision, short sightedness
- liver problems including life-threatening liver failure (hepatocellular liver injury), changes in liver function tests, jaundice (yellowing of the skin or whites of the eyes), inflammation of the pancreas (pancreatitis causing very severe abdominal pain)
- skin rashes, flushing, itching, small pus-containing blisters, muscle and joint pain, darkening of the urine

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

- bone marrow depression disorders such as aplastic anaemia (causing weakness, bruising, making infections more likely)
- urticaria (itchy, pale or red irregular raised patches of skin), fever
- depression, 'pins and needles'
- 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)
- 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)

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 protect from light.

Do not use Metronidazole tablets after the expiry date stated on the label/carton/bottle. 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 Contents of the pack and other information

What Metronidazole tablets contain

- The active substance (the ingredient that makes the tablets work) is metronidazole.
- The other ingredients are carmellose sodium, lactose, povidone, magnesium stearate, maize starch, microcrystalline cellulose, methylhydroxypropylcellulose (E464), macrogol 400 and titanium dioxide (E171).

What Metronidazole tablets look like and contents of the pack

Metronidazole are white, film-coated tablets.

Pack sizes are 21 tablets

Marketing Authorisation Holder

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