

Package leaflet:  
Information for the user  
**Metronidazole 500 mg  
film-coated tablets**  
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 is and what it is 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 is and what it is 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**.
- If you have Cockayne syndrome (see Warnings and precautions)

- 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 **4<sup>th</sup>-9<sup>th</sup> 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**.

If you received this medicine your urine may be darkened.

Cases of severe irreversible liver toxicity/ acute liver failure, including cases with fatal outcomes with very rapid onset after initiation of systemic use of metronidazole, have been reported in patients with Cockayne Syndrome.

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 or have recently taken 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**  
**Alcohol:**

You are advised not to drink alcohol while 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, breast-feeding and fertility**

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**

While taking Metronidazole you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

**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.

**Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially 'sodium-free'.

**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.**

**Elderly**

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

**Adults and adolescents**

**To treat *bacterial vaginosis***

- Adults and children over 10 years: 400mg twice daily for 5-7 days or 2g as a single dose for one day.

**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.

Where re-infection is likely, in adults the consort should receive similar course of treatment concurrently.

**To treat *amoebiasis***

- Adults and children over 10 years:
  - *Invasive intestinal disease in susceptible subjects*: 800mg three times a day for 5 days
  - *Intestinal disease in less susceptible subjects and chronic amoebic hepatitis*: 400mg three times daily for 5- 10 days
  - *Amoebic liver abscess also other forms of extra-intestinal amoebiasis*: 400mg three times daily for 5 days
  - *Symptomless cyst passers*: 400-800mg three times daily for 5-10 daysAlternatively, doses may be expressed by body weight 35 to 50mg/kg daily in 3 divided doses for 5-10 days, not to exceed 2400mg/day

**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.

Alternatively, as expressed in mg per kg of body weight:  
15-40mg/kg/day divided in 2-3 doses.

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

- 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 prevent infections after surgery**

Adults: 400mg 8 hourly during 24 hours immediately, operation followed by post-operative intravenous or rectal administration until the patient is able to take tablets.

**Children**

**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***

- 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 *amoebiasis***

- *Invasive intestinal disease in susceptible subjects*: Aged 7-10 years : 400mg three times daily for 5 days; Aged 3-7 years: 200mg four times daily for 5 days. Aged 1-3 years: 200mg three times daily for 5 days

- *Intestinal disease in less susceptible subjects and chronic amoebic hepatitis: Aged 7-10 years* : 200mg three times daily for 5-10 days; Aged 3-7 years: 100mg four times daily for 5-10 days. Aged 1-3 years: 100mg three times daily for 5-10 days
- *Amoebic liver abscess also other forms of extra-intestinal amoebiasis:* Aged 7-10 years : 200mg three times daily for 5 days; Aged 3-7 years: 100mg four times daily for 5 days. Aged 1-3 years: 100mg three times daily for 5 days
- *Symptomless cyst passers:* Aged 7-10 years : 200-400mg three times daily for 5-10 days; Aged 3-7 years: 100mg-200mg four times daily for 5-10 days. Aged 1-3 years: 100mg-200mg three times daily for 5-10 days. Alternatively, doses may be expressed by body weight 35 to 50mg/kg daily in 3 divided doses for 5-10 days, not to exceed 2400mg/day

**To treat giardiasis**

- 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.

Alternatively, as expressed in mg per kg of body weight:  
15-40mg/kg/day divided in 2-3 doses.

**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.

**To treat infections of the gums (for 3 days)**

- Aged 7-10 years: 100mg three times daily; Aged 3-7 years: 100mg twice daily; Aged 1-3 years: 500mg twice daily.

**To prevent infections after surgery**

- Children greater than 8 weeks to 12 years of age: The usual daily dose is 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. Duration of treatment is usually 7 days.
- Children less than 8 weeks of age:15 mg/kg as a single dose daily or divided into 7.5 mg/kg every 12 hours.
- In new-borns with a gestation age less than 40 weeks: Accumulation of metronidazole can occur during the first week of life, why the concentrations of metronidazole in serum should preferable be monitored after a few days therapy.
- Children under 10 years: A more suitable dosage form should be used for this age group.



**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 (may affect up to 1 in 10,000 people):**

- 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 urine

**Not known (frequency 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 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](http://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.

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

This medicine does not require any special storage conditions.

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 Tablets contains**

- The active substance is Metronidazole. Each film-coated tablet contains 500 mg Metronidazole.
- The other ingredients are Tablet core: Cellulose microcrystalline, starch pregelatinised (maize starch), hydroxypropylcellulose, silica colloidal anhydrous, sodium starch glycolate, stearic acid Tablet coat: Hypromellose 2910 (5cps), polyethylene glycol.

**What Metronidazole film-coated tablets looks like and contents of the pack**

Film-coated tablet  
White to off white, oblong shaped, coated tablets, debossed with 'M' and '500'on one face and a break line on the other face.  
Metronidazole film-coated tablets are available in 21 film-coated tablets.

**Marketing Authorisation Holder**  
Milpharm Limited  
Ares Block, Odyssey Business Park  
West End Road  
South Ruislip HA4 6QD  
United Kingdom

**Manufacturer**  
APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far  
Birzebbugia, BBG 3000  
Malta

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

or  
  
Generis Farmaceutica, S.A.  
Rua João de Deus, n. o 19, Venda Nova, 2700-487, Amadora, Portugal.

**This leaflet was last revised in 12/2022.**