

Metronidazole tablets 500mg

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.

Index

- 1 What Metronidazole tablets are and what they are used for**
- 2 Before you take**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 6 Further information**

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 Before you take

Do not take Metronidazole tablets and **tell** your doctor if you:

- are **allergic** (hypersensitive) to Metronidazole tablets or any of the other ingredients (see section 6)
- are in the **first 3 months of pregnancy** or are **breastfeeding**.

Check with your doctor or pharmacist before taking Metronidazole tablets if you:

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

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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)
- cimetidine (used to treat stomach ulcers)
- oestrogen contraceptives ('the pill').

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.

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.

Sugar intolerance

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

Always take Metronidazole tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

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.

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

Doses:

• Treatment of bacterial infections

Adults and children over 10 years: 500mg eight hourly. Treatment is usually for 7 days but will depend upon your condition.

• Treatment of infection caused by *Trichomonas*

Adults and children over 10 years: 2g as a single dose for 1 day or 250mg twice a day for 6 days. In severe cases 500mg twice a day for 6 days. Your partner should also be treated.

• Treatment of non-specific genital infection in women

Women and girls over 10 years: 500mg twice a day for 7 days, or 2g as a single dose for 1 day only.

• Treatment of *amoebiasis*

Affecting the gut

Adults and children over 10 years: 750mg three times a day for 5 days.

Children 7-10 years: 500mg three times a day for 5 days.

Affecting the gut, liver (treat for 5-10 days) or other part of the body (for 5 days)

Adults and children over 10 years: 500mg three times a day.

Children 7-10 years: 250mg three times a day.

Asymptomatic carriers (cyst passers) treat for 5-10 days

Adults and children over 10 years: 500-750mg three times a day.

Children 7-10 years: 250-500mg three times a day.

• **Treatment of giardiasis**

Adults and children over 10 years: 2g once a day for 3 days or 500mg twice a day for 7 to 10 days
Children 7-10 years: 1g once a day for 3 days or 250mg once a day for 10 days

• **Treatment of infections of the gums (for 3 days) or teeth (for 3-7 days)**

Adults and children over 10 years: 250mg three times a day.

• **Treatment of infected leg ulcers or pressure sores (for 7 days)**

Adults and children over 10 years: 500mg three times a day

• **Treatment of stomach ulcers caused by *Helicobacter pylori***

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

• **Prevention of infections after surgery**

Adults and children over 10 years: 1g as a single dose 24 hours before surgery then, 500mg at 8 hourly intervals during the 24 hours before the operation.

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 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 the 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 the 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, Metronidazole tablets can cause side effects, particularly when you first start taking it, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

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.

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

- **Blood:** your medicine may alter the numbers and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who might want you to have a blood test.
- **Nervous system:** drowsiness, dizziness, headache, poor co-ordination or muscle control, hallucinations, double vision, short sightedness, confusion, depression, 'pins and needles', fits, numbness, tingling, pain or a feeling of weakness in the arms or legs.
- **Stomach and intestines:** unpleasant taste in the mouth, furred tongue, taste disorders, mouth ulcers, feeling or being sick, loss of appetite, diarrhoea, stomach pain and upset stomach.

- **Liver and bile ducts:** jaundice (yellowing of the skin or whites of the eyes), inflammation of the pancreas (pancreatitis causing very severe abdominal pains), changes in liver function tests.
- **Skin:** skin rashes, itching, small pus-containing blisters, erythema multiforme (circular, irregular red patches).
- **Muscles and bones:** muscle and joint pain.
- **Kidneys and urinary system:** darkening of the urine.

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight 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 Further 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

Actavis Group PTC ehf, Reykjavikurvegi 76-78, Hafnarfjörður, Iceland.

Manufacturer

Balkanpharma-Dupnitsa AD
3, Samokovsko shosse Str.
2600 Dupnitsa
Bulgaria

Distibutor

Actavis, Barnstaple, EX32 8NS, UK

Date of last revision: March 2010