

Metronidazole 500mg Film-coated Tablets

Patient Information Leaflet

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.

Your medicine is called Metronidazole 500mg Film-coated Tablets. Throughout this leaflet it will be referred to as Metronidazole tablets. Please note that the leaflet also contains information about another strength of the medicine Metronidazole 400mg and 800mg.

What is in this leaflet

- 1 What Metronidazole tablets are and what they are 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 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 have **epilepsy** or have ever had **fits**
- * 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 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.

Tell your doctor immediately and stop taking metronidazole if you develop:

- * Stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, vertigo, jaundice, dark urine, putty or mastic-coloured stools or itching.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP) have been reported with the use of metronidazole:

- * SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters 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 for 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 tablets and contact your doctor or seek medical attention immediately.**

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)
- * 5-fluorouracil (used to treat some forms of cancer)
- * busulfan for leukaemia (cancer of the blood cells)
- medicines that may cause heart rhythm disturbances (so-called QT prolongation which can be seen on ECG) such as:
 - certain anti-arrhythmics (medicines for heart rhythm disturbances)
 - certain antibiotics
 - medication primarily used to manage psychosis (including delusions, hallucinations, paranoia or disordered thought).

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

Metronidazole tablets with 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

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.

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.

Driving and using machines

Metronidazole tablets may make you feel drowsy, dizzy, experience vertigo (spinning sensation), confusion, affect your vision, cause convulsions (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 by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

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

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 recommended doses less than 500mg (one tablet), an alternative dosage form/strength should be used to achieve correct dosing for your treatment.

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

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 exceed 2g/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.
- * Alternatively, 35-50mg/kg/day in 3 divided doses for 5 to 10 days. Doses should not exceed 2.4g/day.
- * 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.
- * Alternatively, 15-40mg/kg/day divided in 2 or 3 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 3-7days)

- * 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 treat stomach ulcers caused by *Helicobacter pylori*

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

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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.

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

4 Possible side effects

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

Stop taking Metronidazole tablets and contact your doctor or go to a hospital immediately if you notice any of the following serious side effects:

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

- * allergic reactions: skin rash, which may be itchy, swelling of the face, lips, tongue or throat, fever or difficulty in breathing.

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

- * unexpected infections or sore throats, mouth ulcers, bruising, nosebleeds, bleeding gums, or severe tiredness. This could be caused by a problem with the numbers and types of blood cells. You should tell your doctor who might want you to have a blood test
- * symptoms of a severe but rare brain disease (encephalopathy). Symptoms vary but you might get fever, stiff neck, headache, experience vertigo, see or hear things that aren't there
- * symptoms of Cerebellar syndrome (poor co-ordination or muscle control, involuntary shakiness, uncontrolled eye movements, speech disorders, walking abnormally)
- * yellowing of the skin and eyes. This could be due to a liver problem (jaundice)
- * severe stomach pain which may reach through to your back (pancreatitis)
- * 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).

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

- * short periods of amnesia caused by transient epileptic seizures
- * 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)
- * erythema multiforme (circular, irregular red patches on the skin, particularly on the hands and feet)
- * 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
- * acute liver failure in patients with Cockayne Syndrome (see section 2 "Warnings and precautions").

Tell your doctor if any of the following side effects get serious or last longer than a few days, or you notice any other effects not listed:

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

- * mental health problems including confusion, hallucinations (seeing or hearing things that are not there)
- * drowsiness, dizziness, headache, fits
- * double vision, short sightedness
- * liver problems including life-threatening liver failure (hepatocellular liver injury), changes in liver function tests
- * skin rashes, flushing, itching, small pus-containing blisters
- * muscle and joint pain
- * darkening of the urine.

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

- * tingling, pain or a feeling of weakness in the arms or legs, numbness
- * urticaria (itchy, pale or red irregular raised patches of skin), fever
- * depression
- * pain in your eyes (optic neuritis)
- * hearing impairment/hearing loss
- * ringing in the ears (tinnitus)
- * vertigo (spinning sensation)
- * changes in taste, furred tongue, inflammation in the mouth, feeling or being sick, loss of appetite, diarrhoea, stomach pain and upset stomach
- * heart rhythm disturbances (so-called QT prolongation which can be seen on ECG), particularly when Metronidazole tablets are used with other medicines that may cause heart rhythm disturbances.

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 Website: 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 out of the sight and reach of children.**
- * Do not store above 25°C.
- * Protect from light.
- * Store in the original package.
- * Do not take Metronidazole after the expiry date shown on the blister or carton. The expiry date refers to the last day of that month.
- * If your doctor tells you to stop using this medicine, take any remaining tablets back to the pharmacist for safe disposal. Only keep this if your doctor tells you to.
- * If your tablets become discoloured or shows any other signs of deterioration consult your pharmacist who will tell you what to do.
- * 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 contains:

- * Each tablet contains Metronidazole 500mg.
- * The other ingredients are lactose monohydrate, microcrystalline cellulose, titanium dioxide (E171), maize starch, carmellose sodium, povidone, magnesium stearate, methylhydroxypropylcellulose, macrogol 400.

What Metronidazole looks like and contents of the pack

White, bi-convex, film-coated tablet marked CL above and J below a scoreline and plain on the reverse.

Each pack contains 20 or 30 Tablets.

Manufacturer and Licence Holder

Manufactured by Generis Farmaceutica, S.A., Rua João de Deus, 19, 2700-487, Amadora, Portugal and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

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