

- 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.

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 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 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 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 look 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.

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