

PACKAGE LEAFLET: INFORMATION FOR THE USER

MEDAZOL

250mg Tablets

METRONIDAZOLE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT MEDAZOL IS AND WHAT IS IT USED FOR

Medazol 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 MEDAZOL

Do not take Medazol tablets and tell your doctor if you:

- are allergic (hypersensitive) to Medazol tablets or any of the other ingredients
- are in the first 3 months of pregnancy or are breastfeeding.

Check with your doctor or pharmacist before taking Medazol 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

Medazol 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 Medazol 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

Medazol 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 Medazol tablets before the test.

3. HOW TO TAKE MEDAZOL

Always take Medazol 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: 800mg followed by 400mg at eight hourly intervals.

Treatment is usually for 7 days but will depend upon your condition.

- Treatment of 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.

Children under 8 weeks: 15mg/kg/day as a single dose or divided into 7.5mg/kg every 12 hours.

- Treatment of 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 to 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.

- Treatment of 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.

- Treatment of 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.

- Treatment of 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: 1g 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.

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

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

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

Adults and children over 10 years: 400mg 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: 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: A more suitable dosage form should be used.

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, Medazol 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:

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 hallucinations (seeing or hearing things that are not there), drowsiness, dizziness, fits, tingling, pain or a feeling of weakness in the arms or legs, numbness
- Encephalopathy (headaches, light sensitivity, confusion, fever, paralysis, stiff neck)
- Cerebellar syndrome (poor co-ordination or muscle control, involuntary shakiness, uncontrolled eye movements, speech disorders, walking abnormally)
- double vision, short sightedness
- 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), flushing
- skin rashes, itching, small pus-containing blisters, muscles 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'
- 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)

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 MEDAZOL

Keep out of the reach and sight of children.

Store below 25°C protect from light.

Do not use Medazol 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.