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 vours.
- 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

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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.

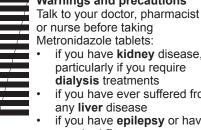
2. What you need to know before you take Metronidazole Tablets Do not take Metronidazole Tablets

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



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.
- 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,

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

SJS/TEN can appear initially as

reddish target-like spots or circular patches often with central blisters on

of metronidazole:

- 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 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 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 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)
- blood cells) medicines that may cause heart rhythm disturbances (so-called QT prolongation which can be seen on

busulfan for leukaemia (cancer of the

- 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 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

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. Information on sodium content

This medicine contains less than 1 mmol

sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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 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

Children under 8 weeks: 15mg/kg/

day as a single dose or divided into

the severity of the infection.

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

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

to three times daily for 7 days. Doses

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
- Adults and children over 10 years: 400mg-800mg three times a day for

dose.

To treat amoebiasis

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.

Black

Metronidazole tablets work.

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- 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

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)

for this age group.

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 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.

their advice. 4. Possible side effects

Talk to your doctor before you stop taking the tablets and follow

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)
- may reach through to your back (pancreatitis) you develop a red, scaly widespread rash with bumps under the skin

severe stomach pain which

and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

Not known (frequency cannot be

spinal cord (meningitis)

- 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

- 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.

Tablets Keep this medicine out of the sight and

How to store Metronidazole

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. 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

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**

White to off white, oblong shaped,

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

pack

Film-coated tablet

Milpharm Limited

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

United Kingdom Generis Farmaceutica, S.A. Rua João de Deus, n. o 19, Venda

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