

Metronidazole Rosemont 200mg/5ml Oral Suspension

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. See section 4.

What is in this leaflet

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1. What Metronidazole Rosemont is and what it is used for

The name of your medicine is Metronidazole Rosemont 200mg/5ml Oral Suspension (called Metronidazole in this leaflet). It contains metronidazole benzoate. This belongs to a group of medicines called antibacterials.

Metronidazole can be used for:

Adults and children over 1 year

- preventing infections after you have an operation
- treating infections, including infections of your blood, brain, lungs, bones, lining of your abdomen, pelvis and infections following childbirth or around the area where you had an operation
- treating trichomoniasis. This is a sexually transmitted infection, in both males and females
- treating amoebiasis - an infection of your intestine or liver caused by a parasite
- treating giardiasis - an infection that causes swelling of your intestines.

Adults and children over 10 years only

- treating vaginosis - an infection and swelling of your vagina
- treating swollen gums and ulcers in your mouth (gingivitis) and other dental infections
- treating ulcers and pressure sores on your leg.

Children

It can also be used in children to treat a bacterial infection in the stomach (*Helicobacter pylori*).

Newborns (full term)

It can be used in full term newborns for treating bacteria infections and preventing infections after an operation.

2. What you need to know before you take Metronidazole Rosemont

Do not take Metronidazole and tell your doctor 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, itching or shortness of breath
- you are pregnant, think you are pregnant or breast feeding.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking Metronidazole.

Warnings and precautions

Talk to your doctor before taking Metronidazole if:

- you have liver problems
- you have a disease of the nervous system
- you are having haemodialysis.

If you are on this medicine for more than 10 days, your doctor may give you some tests.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Metronidazole.

Cases of severe liver toxicity/acute liver failure, including cases with a fatal outcome, in patients with Cockayne syndrome have been reported with product 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.

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 and contact your doctor or seek medical attention immediately.

Tell your doctor immediately and stop taking metronidazole if you develop: stomach pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.

Other medicines and Metronidazole

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Metronidazole can affect the way some other medicines work. Also, some medicines can affect the way Metronidazole works.

In particular, tell your doctor if you are taking any of the following:

- warfarin - used to thin your blood
- lithium - used to treat depression
- phenobarbital, phenytoin or carbamazepine - used to treat epilepsy
- 5-fluorouracil - used to treat cancer
- busulfan – used to treat leukaemia
- ciclosporin or tacrolimus - used after organ transplants
- disulfiram – used to treat alcoholism.

Metronidazole with food and drink

Do not drink alcohol whilst taking Metronidazole and for 48 hours after finishing the treatment. Drinking alcohol may cause unpleasant side effects such as nausea, vomiting, pain in and around your stomach area (the abdomen), hot flushes, palpitations and headaches.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine. You should not take Metronidazole if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

Metronidazole may make you feel drowsy, dizzy or confused. It may cause you to see and hear things that are not there (hallucinations), have fits or give you blurred or double vision. If you are affected, do not drive or operate machines.

Metronidazole Rosemont contains, methyl, ethyl and propyl parahydroxybenzoates, glucose, sucrose, sorbitol and propylene glycol

- methyl, ethyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may not happen straight away
- glucose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, you must contact your doctor before taking this medicine. It may also be harmful to teeth.
- This medicine contains 113.7 mg sorbitol (E420) in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- This medicine contains 31.1 mg propylene glycol (E1520) in each ml.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- If you are pregnant, breast-feeding, suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to take Metronidazole Rosemont

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure. The different routines you might follow are shown below.

Taking this medicine

- This medicine contains 200mg of metronidazole in each 5ml.
- Take this medicine by mouth.
- Always shake the bottle before use.
- Complete the full course of this medicine.

How much to take

The usual doses for adults and children are:

What you're taking the medicine for	Number of days you will take the medicine for	How much to take – Adults and children over 12 years of age	How much to take – Children under 12 years of age
Prevention of infections after surgery	1	10ml (400mg) three times during the day before the operation	Your doctor will work out the right dose based on your child's weight.
Bacterial infections	-	A 20ml (800mg) dose followed by 400mg (10ml) three times a day	

Other infections

Adults and children over 10 years of age:

What you're taking the medicine for	Number of days you will take the medicine for	How much to take – Adults and children over 10 years of age
Trichomoniasis	1	50ml (2000mg) once a day
	or 5 to 7	10ml (400mg) twice a day
	or 7	5ml (200mg) three times a day
Vaginosis	1	50ml (2000mg) once a day
	or 5 to 7	10ml (400mg) twice a day
Amoebiasis	5 to 10	10ml (400mg) to 20ml (800mg) three times a day
Giardiasis	3	50ml (2000mg) once a day
	or 5	10ml (400mg) three times a day
	or 7 to 10	12.5ml (500mg) twice a day
Gingivitis	3	5ml (200mg) three times a day
Dental infections	3 to 7	5ml (200mg) three times a day
Leg ulcers and pressure sores	7	10ml (400mg) three times a day

Children under 10 years of age:

What you're taking the medicine for	Number of days you will take the medicine for	How much to take – Children aged 7-10 years	How much to take – Children aged 3-7 years	How much to take – Children aged 1-3 years
Trichomoniasis	7	Your doctor will work out the right dose based on your child's weight. This should not exceed 2000mg a day.		
Amoebiasis	5 to 10	5ml (200mg) to 10ml (400mg) three times a day	2.5ml (100mg) to 5ml (200mg) four times a day	2.5ml (100mg) to 5ml (200mg) three times a day
		Your doctor will work out the right dose based on your child's weight. This should not exceed 2400mg a day.		
Giardiasis	3	25ml (1000mg) once a day	15ml (600mg) to 20ml (800mg) once a day	12.5ml (500mg) once a day
		Your doctor will work out the right dose based on your child's weight.		
Gingivitis	3	2.5ml (100mg) three times a day	2.5ml (100mg) twice a day	1.25ml (50mg) three times a day

Children – treatment for a bacterial infection in the stomach (*Helicobacter pylori*)

Your child will be given Metronidazole with other medicines. Your doctor will work out the right dose based on your child's weight.

This should not exceed 500mg twice a day.

Older people and those with liver problems

Your doctor may prescribe a lower dose than that given to adults. This is because you may be more sensitive to the medicine.

If you take more Metronidazole than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Metronidazole

Do not take a double dose (two doses at the same time) to make up for a forgotten dose. Take your next dose as soon as you remember, then go on as before. However, if it is nearly time for the next dose, skip the missed dose.

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

4. Possible side effects

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

Stop taking Metronidazole and see a doctor or go to a hospital straight away if:

- you get a brain disease (encephalopathy) which is a serious but very rare side effect. Symptoms vary but you might get a fever, stiff neck, headache, see or hear things that aren't there. You might also have problems using your arms and legs, problems with speaking or feeling confused
- you get 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)
- you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash or nettle rash. This may mean you are having an allergic reaction to Metronidazole
- blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Steven Johnson Syndrome' which is a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. Sometimes called Toxic epidermal necrolysis.
- 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). Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Talk to your doctor straight away if you notice the following side effects:

- yellowing of your skin and the whites of your eyes (jaundice)
- blood problems. You may notice signs such as high temperature or chills, unexpected infections, bruising, sore throat, ulcers in your mouth or throat, bleeding gums and unusual tiredness
- severe stomach pain which may reach through to your back (pancreatitis).

Tell your doctor or pharmacist if you notice any of the following side effects: Very Rare: may affect up to 1 in 10,000 people

- fits (convulsions)
- feeling confused
- seeing or hearing things that are not there (hallucinations)
- temporary affects on your eyesight, such as difficulty in focusing
- drowsiness and dizziness
- clumsiness or poor co-ordination
- pain and swelling of your skin, skin rashes or flushing
- headache
- itching
- darkening of your urine
- pains in your joints or muscles
- liver problems including life-threatening liver failure (hepatocellular liver injury).

Frequency not known

- numbness, tingling, pain or feeling weak in your arms and legs
- unpleasant taste in your mouth or a furry tongue
- feeling or being sick, upset stomach or diarrhoea
- loss of appetite
- fever
- feeling depressed
- pain in your eyes (optic neuritis)
- hearing impairment/ hearing loss
- ringing in the ears (tinnitus)
- you get a rash or skin discolouration with or without raised areas which often reoccurs at the same location each time the drug is taken
- acute liver failure in patients with Cockayne Syndrome (see section 2 "Warnings and precautions").

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. 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 Rosemont

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the label and carton (Exp: month, year).
- The expiry date refers to the last day of that month.
- Do not use Metronidazole Rosemont if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist.
- 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 to protect the environment.

6. Contents of the pack and other information

What Metronidazole Rosemont contains

- The active substance is metronidazole benzoate. Each 5ml contains 320mg metronidazole benzoate. This is equivalent to 200mg metronidazole.
- The other ingredients are methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), propylene glycol (E1520), dispersible cellulose (E460), colloidal silicon dioxide, sucrose, glucose, sorbitol solution (E420), glycerol (E422), polysorbate 80, lemon flavour, orange flavour and purified water.

What Metronidazole Rosemont looks like and contents of the pack

A creamy white suspension with an odour of citrus.

It comes in a brown glass bottle holding 100ml of suspension.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 11/2022