

Patient Information Leaflet

Metronidazole 200mg/5ml Oral Suspension

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



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1. WHAT IS METRONIDAZOLE ORAL SUSPENSION AND WHAT IS IT USED FOR

The name of your medicine is Metronidazole 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. BEFORE YOU TAKE METRONIDAZOLE ORAL SUSPENSION

Do not take Metronidazole and tell your doctor if:

- you are allergic (hypersensitive) to metronidazole or any other ingredients in this liquid (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.

Take special care with Metronidazole

Before you take Metronidazole, tell your doctor if:

- you have liver problems
- you have a disease of your brain or spinal column
- 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.

Taking other medicines

Please 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

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- lithium - used to treat depression
- phenobarbital - used to treat epilepsy
- 5-fluorouracil - used to treat cancer
- busulfan – used to treat leukaemia
- ciclosporine - used after organ transplants.

Taking 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.

Important information about what is in Metronidazole Oral Suspension

This medicine contains:

- methyl, ethyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may not happen straight away
- glucose, sucrose and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, you must contact you doctor before taking this medicine. It may also be harmful to teeth.

3. HOW TO TAKE METRONIDAZOLE ORAL SUSPENSION

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

Other infections continued

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
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.

Continued overleaf

4. POSSIBLE SIDE EFFECTS

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

If you have an allergic reaction to Metronidazole, see a doctor straight away

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

If you get any of the following side effects, stop taking Metronidazole and see your doctor as soon as possible:

- fits (convulsions)
- pain and swelling of your skin or skin rashes
- severe pain in and around your stomach area (the abdomen)
- yellowing of your skin and the whites of your eyes (jaundice)
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness
- drowsiness and dizziness
- clumsiness or poor co-ordination
- temporary affects on your eyesight, such as difficulty in focusing
- numbness, tingling, pain or feeling weak in your arms and legs
- feeling confused
- seeing or hearing things that are not there (hallucinations).

Tell your doctor if you get any of these side effects:

- feeling or being sick, upset stomach or diarrhoea
- unpleasant taste in your mouth or a furry tongue
- loss of appetite
- itching
- headache
- darkening of your urine
- pains in your joints or muscles.

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.

5. HOW TO STORE METRONIDAZOLE ORAL SUSPENSION

- Keep out of the reach and sight of children
- Do not store above 25°C
- Do not use 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 Oral Suspension if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist
- 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. FURTHER INFORMATION

What Metronidazole 200mg/5ml Oral Suspension contains

- The active ingredient is metronidazole benzoate
- 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 200mg/5ml Oral Suspension 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.

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