

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Metronidazole 200 mg Film-coated Tablets**  
**Metronidazole 400 mg Film-coated Tablets**  
**metronidazole**

PHARMACODE

**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:**

1. What Metronidazole Tablet is and what it is used for
2. What you need to know before you take Metronidazole tablets
3. How to take Metronidazole Tablet
4. Possible side effects
5. How to store Metronidazole Tablet
6. Contents of the pack and other information

**1. What Metronidazole Tablet is and what it is used for**

Metronidazole tablet contains metronidazole as active ingredient, which belongs to the group of medicines called antibiotics. It works by killing bacteria and parasites that cause infections in your body. It can be used to:

- Treat infections of the blood, brain, lung, bones, genital tract, pelvic area, stomach and intestines
- Treat gum ulcers and other dental infections
- Treat infected leg ulcers and pressure sores
- Prevent infections after surgery

If you need any further information on your illness, speak to your doctor

**2. What you need to know before you take Metronidazole Tablet**

**Do not take Metronidazole Tablet :**

- 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.

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

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Metronidazole Tablets if:

- You have or have ever had a liver problem
- You are having kidney dialysis (see section 3: 'People having kidney dialysis')
- You have a disease of the nervous system

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking your medicine. Do this even if they have applied in the past.

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

If you are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently while you are being treated with Metronidazole Tablet and afterwards.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP) have been reported with the use of Metronidazole Tablet.

- 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 Tablet and contact your doctor or seek medical attention immediately.

Tell your doctor immediately and stop taking Metronidazole Tablet 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 Tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Metronidazole Tablet can affect the way some other medicines work. Also, some other medicines can affect the way Metronidazole Tablet works.

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

- Medicines used to thin the blood such as warfarin
- Lithium for mental illness
- Phenobarbital or phenytoin for epilepsy
- 5 fluorouracil for cancer
- Busulfan for leukaemia (cancer of the blood cells)
- Ciclosporin- to prevent the rejection of organs after transplant
- Disulfiram for alcoholism

If you are not sure, talk to your doctor or pharmacist before taking Metronidazole Tablet.

**Metronidazole Tablet with food, drink and alcohol**

Do not drink any alcohol while you are taking Metronidazole Tablet and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole Tablet might cause unpleasant side effects, such as feeling sick (nausea), being sick (vomiting), stomach pain, hot flushes, very fast or uneven heartbeat (palpitations) and headache.

**Pregnancy and breast-feeding**

Tell your doctor before using Metronidazole Tablet if:

- You are pregnant, might become pregnant or think you may be pregnant. Metronidazole Tablet should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to use Metronidazole Tablet if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

While taking Metronidazole Tablet you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). If this happens, do not drive or use any machinery or tools.

**Tests**

Your doctor may wish to carry out some tests if you have been using this medicine for more than 10 days.

**3. How to take Metronidazole Tablet**

**Taking your medicine**

Always take Metronidazole Tablet exactly as your doctor has told you. It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets whole with a drink of water
- Do not crush or chew the tablets
- Take these tablets during or just after a meal
- The dose of Metronidazole Tablet will depend on your needs and the illness being treated
- The length of your treatment will depend on the type of illness you have and how bad it is

The usual dose for adults and children is given below:

**To treat bacterial infection**

- Adults**
- The initial dose is 800mg
- After 8 hours take another dose of 400 mg and repeat this dose every 8 hours

**Children**

- Your doctor will work out how much your child should take depending on their weight
- Repeat the dose every 8 hours
- If your child is a baby under 8 weeks of age, your doctor will give them one daily dose or two separate doses 12 hourly

**To prevent infections from happening after surgery**

- Adults**
- Start Taking Metronidazole Tablet 24 hours before your operation
- Take 400 mg of Metronidazole Tablet every 8 hours
- After the operation you may be given metronidazole either through a drip into a vein or rectally as a suppository until you are able to take tablets again

**Children**

- Give your child Metronidazole Tablets 1-2 hours before their operation
- Your doctor will work out how much your child should take depending on their weight
- After the operation your child may be given metronidazole either through a drip into a vein or rectally as a suppository until they are able to take tablets again

**Other types of infections**

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much Metronidazole Tablet you need to take and how often. This will depend on your illness and how bad it is. The pharmacist's label on the packaging will tell you how many tablets to take and how often to take them.

**People having kidney dialysis**

Kidney dialysis removes Metronidazole Tablet from your blood. If you are having kidney dialysis you must take this medicine after your dialysis treatment.

**People with liver problems**

Your doctor may tell you to use a lower dose or to use the medicine less often.

**If you take more Metronidazole Tablet than you should**

If you take more Metronidazole Tablet than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the pack and any tablets left with you. This is so the doctor knows what you have taken.

**If you forget to take Metronidazole Tablet**

If you forget to take Metronidazole Tablet, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Metronidazole**

It is important that you complete your full course of antibiotics; do not stop taking the tablets early if you feel better.

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 Tablet can cause side effects, although not everybody gets them.

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

- 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 (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Metronidazole Tablet.
- A serious but very rare side effect is a brain disease (encephalopathy).

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 feel confused.

- 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. Stop using Metronidazole Tablet if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
- 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 Tablet 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 the skin and eyes. This could be due to a liver problem (jaundice).
- Unexpected infections, mouth ulcers, bruising, bleeding gums, or severe tiredness. This could be caused by a blood problem.
- 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 (affects less than 1 in 10 000 people)**
- Fits (convulsions)
- Mental problems such as feeling confused and seeing or hearing things that are not there (hallucinations)
- Problems with your eyesight such as blurred or double vision
- Skin rash or flushing
- Headache
- Darkening of the urine
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Liver problems including life-threatening liver failure (hepatocellular liver injury)

**Not known (frequency cannot be estimated from the available data)**

- Numbness, tingling, pain, or a feeling of weakness, in the arms or legs
- Unpleasant taste in the mouth

- Furred tongue
- Patches of skin redness on the face, arm, hands and feet (erythema multiforme)
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite
- Fever
- Feeling depressed
- Pain in your eyes (optic neuritis)

- 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)
- 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")

**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.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date shown on the pack.
- 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 Tablet contains**

Each tablet contains 200mg or 400mg of metronidazole as the active substance.

Other ingredients are: Cellulose Microcrystalline, Crospovidone, Hydroxypropylcellulose, Silica Colloidal anhydrous, Stearic acid.

The coating of the tablets contains: Opadry White (for 200mg) which contains HPMC 2910 (E464), Titanium dioxide (E171), Macrogol (E1521), Opadry Yellow (for 400mg) which contains HPMC 2910 (E464), Titanium dioxide (E171), Macrogol (E1521), Iron Oxide Yellow (E172)

**What Metronidazole Tablet looks like and contents of the pack**

Metronidazole 200 mg Film-coated Tablets are White to off white circular (8mm), biconvex film coated tablets with '200' debossed on one side and plain on other side.

Metronidazole 400 mg Film-coated Tablets are Yellow, circular (11mm), biconvex, film coated tablet with '400' debossed on one side and plain on other side.

Metronidazole Tablets are available in cartons containing blister packs of Aluminium-PVC/PVDC foil of 7's, 10's, 14's, 21's, 28's, 30's, 84's and 100's along with a leaflet inside and HDPE bottles of 100's and 250's in a carton along with a leaflet inside.

Not all pack sizes may be marketed.

**Marketing Authorization Holder**

**Flamingo Pharma (UK) Ltd.**

1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.

**Manufacturer**

**Flamingo Pharma (UK) Limited**

The Bloc, 38 Springfield Way, Anlaby, Hull, HU10 6RJ, United Kingdom.

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