**1. WHAT METRONIDAZOLE TABLETS ARE AND WHAT THEY ARE USED FOR**

The name of this medicine is metronidazole. This belongs to a 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 TO KNOW BEFORE YOU TAKE METRONIDAZOLE TABLETS**

- Do not take Metronidazole Tablets if
  - You are allergic (hypersensitive) to metronidazole, nitroimidazoles (e.g. tinidazole) or any of the other ingredients in your medicine (listed in Section 4).
  - You are affected by Cockayne syndrome, your doctor should also monitor your liver function frequently.

**3. HOW TO TAKE METRONIDAZOLE TABLETS**

Telling your doctor immediately and stop taking metronidazole if you develop:
- Stomach pain, anaemia, 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 can affect the way some other medicines work. Also, some other medicines can affect the way Metronidazole works.

In particular, tell your doctor if you are taking:
- Anticoagulants (blood thinning agents), such as warfarin. The dosage of warfarin may need to be reduced when you are taking this drug.
- Lithium for mental illness. If taken at the same time as metronidazole, the kidneys may be affected.
- Medicines used to treat epilepsy such as phenytoin, primidone, phenobarbital
- 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.

**Metronidazole Tablets with food and drink**

Do not drink any alcohol while you are taking metronidazole and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole 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 if:
- You are pregnant, might become pregnant or think you may be pregnant. Metronidazole should not be taken during pregnancy unless considered absolutely necessary.
- You are breast-feeding. It is better not to use Metronidazole 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 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.

**4. POSSIBLE SIDE EFFECTS**

The most common side effects of Metronidazole are:

- Nausea, vomiting, stomach pain, diarrhoea, or constipation
- Feeling sleepy, drowsy, dizzy, or confused
- Being able to see or hear things that are not there (hallucinations)
- Temporary eyesight problems (such as blurred or double vision)

If this happens, do not drive or use any machinery or tools.

**5. HOW TO REPORT SUSPECTED SIDE EFFECTS**

Tell your doctor immediately and stop taking metronidazole if you develop:
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If this happens, do not drive or use any machinery or tools.

**5. HOW TO REPORT SUSPECTED SIDE EFFECTS**

Tell your doctor immediately and stop taking metronidazole if you develop:
- Stomach pain, anaemia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, putty or mastic coloured stools or itching.
- After the operation you may be given Metronidazole orally or rectally. If you are unable to take tablets again:

Children
- Start giving 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 orally 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 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 as you will have taken.

People having kidney dialysis
- If you have 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 Tablets than you should:
- If you take more metronidazole than you should, contact your doctor or nearest hospital emergency department immediately. Always take the box, this leaflet and any tablets that are left over with you, if you can. This is so the doctor knows what you have taken.

If you forget to take Metronidazole Tablets:
- If you miss a dose, take it as soon as you remember and carry on as usual. Do not take a double dose to make up for a forgotten 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 Tablets 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 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.
- 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 of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.
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- 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 the skin and eyes. This could be due to a liver problem (jaundice).
- 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 of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Metronidazole if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

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 blurring or double vision
- Skin rash and 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)
- Very rare (affects less than 1 in 10,000 people)
- Severe stomach pain which may reach through to your back (pancreatitis)
- 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)

5. HOW TO STORE METRONIDAZOLE TABLETS
- Keep this medicine out of the sight and reach of children.
- Store below 25°C in original packaging (protect from light)
- Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.
- Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Metronidazole Tablets contain
- Each tablet contains, 200mg or 400mg of metronidazole as the active substance.
- The other ingredients are povidone, magnesium stearate, colloidal anhydrous silica and maize starch.

What Metronidazole Tablets look like and contents of the pack
- The tablets are off-white coloured, round, biconvex and uncoated, engraved with either “M2 200” (200mg) or “M2 400” (400mg) and a breakline on one side whilst plain on the other. Metronidazole Tablets 200mg are available in containers of 7, 14, 15, 21, 28, 42, 56, 70, 84, 100, 250, 500 and 1000 as well as in bottles containing 50 tablets.
- Metronidazole Tablets 400mg are available in containers of 28, 30, 50, 60, 90, 112, 120, 140, 168, 180, 500 and 1000 tablets.
- They are also available in blister packs of 7, 14, 15, 21, 28, 42, 56, 70 and 84 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Milpharm Limited
Marketing Authorisation Holder and Manufacturer: Milpharm Limited, Aria, Odyssey Business Park, West End Road, South Ruislip, HA4 6QD United Kingdom

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