WHAT METRONIDAZOLE IS AND WHAT IT IS USED FOR

Metronidazole Tablets are used to prevent and treat a variety of infections in adults and children caused by a range of bacteria and protozoa, such as:

- prevention of bacterial infections after surgery and the treatment of infected wounds after surgery
- treatment of susceptible bacterial infections such as infections of the blood, abdomen, lungs, bones, pelvic area, brain or wound infections after a surgical operation
- treatment of certain bacterial and protozoal infections of the genital tract
- treatment of infections of the intestinal tract caused by parasitic micro-organisms
- treatment of infected pressure sores and leg ulcers
- treatment of dental infections and ulceration of the gums.

HOW TO TAKE METRONIDAZOLE

DO NOT take Metronidazole and contact your doctor if you:

- are allergic (hypersensitive) to metronidazole or any of the other ingredients of this medicine, see section 7 for the full list of ingredients
- are in the first 3 months of pregnancy or are breast-feeding.
- have a disease which is affecting your brain, nervous system or spinal cord
- are taking other medicine that could interact with metronidazole, such as:
- disulfiram (used to control the effects of excess stomach acid such as ulcers and heartburn), as this may possibly increase the unwanted effects of metronidazole
- "the pill" (oral contraceptive), as metronidazole may reduce its effectiveness
- disulfiram (used for chronic alcohol dependence), as metronidazole may increase the risk of developing severe behavioural reactions
- have diabetes and need insulin
- have an intolerance to some sugars, e.g. lactose
- have epilepsy or have ever had fits
- have jaundice (a yellowing of the skin or white part of the eye)
- have porphyria (a genetic disease that can cause skin blisters, abdominal pain and brain/nervous system disorder)
- have any disorder of the blood and/or blood cells
- have been exposed to any sexually transmitted disease.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, to check that the medicine is safe for you to use.

Important information about some of the ingredients of Metronidazole

- If you are to take Metronidazole Tablets for more than 10 days, you may need to have regular blood tests.
- If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if they have the same symptoms as you.
- You should stop taking your tablets if you think they are making you feel unwell. If you think the medicine is not working, or if your infection is getting worse, tell your doctor or pharmacist.
- This medicine may cause dizziness. If you feel dizzy, do not drive or operate any machinery until you know how the tablets will affect you.
- This medicine may cause sleepiness or drowsiness. You should not drive or operate machinery if you feel sleepy.
- Do not use Metronidazole after the expiry date that is stated on the outer packaging. The expiry date is the last day of the month stated.
- Store in a cool, dry place and protect from light. Store in the original package.

WHAT YOU HAVE TO DO WITH ANY LEFTOVER MEDICINE

Do not use Metronidazole Tablets after the expiry date. If you do not finish the course of tablets you have been prescribed, you should ask your pharmacist how to safely dispose of any tablets left over.

HOW TO TAKE METRONIDAZOLE

Always take Metronidazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water. They should not be chewed. It is recommended that the tablets be taken during or after a meal.

Your doctor will discuss how much Metronidazole you need to take and how often. This will depend on the illness you are being treated for and how bad it is. The label stuck on the packaging by the pharmacist will tell you exactly how many tablets to take and how often to take them.

The following is a guide to the doses for treatment of bacterial infections.

<table>
<thead>
<tr>
<th>Infection</th>
<th>Dose</th>
<th>Length of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult and children over 12 years</td>
<td>400 mg daily or 400 mg three times a day</td>
<td>3 days</td>
</tr>
<tr>
<td>Adult and children under 12 years</td>
<td>7.5 mg/kg twice a day</td>
<td>3 days</td>
</tr>
<tr>
<td>Adult and children under 12 years</td>
<td>7.5 mg/kg once a day</td>
<td>7 days</td>
</tr>
<tr>
<td>Prevention of anaerobic infections after an operation</td>
<td>400 mg every 8 hours during the 34 hours before an operation.</td>
<td>N/A</td>
</tr>
<tr>
<td>Prevention of anaerobic infections after an operation</td>
<td>20 to 30 mg/kg as a single dose</td>
<td>N/A</td>
</tr>
</tbody>
</table>

HOW TO TAKE METRONIDAZOLE

Before you start to take this medicine if you:

- have a disease which is affecting your brain, nervous system or spinal cord
- have ever had or currently have any problems with your liver
- have epilepsy or have ever had fits
- have porphyria (a genetic disease that can cause skin blisters, abdominal pain and brain/nervous system disorder)
- have any disorder of the blood and/or blood cells
- have been exposed to any sexually transmitted disease.

Taking other medicines

Talk to your doctor or pharmacist if you are taking any of the following:

- blood thinning tablets (anticoagulants) as metronidazole may increase their effect. If your doctor thinks you need both medicines, it may be necessary to reduce the dose of the anticoagulant and/or increase the frequency of your blood checks
- lithium (used for depression and other severe behavioural disorders) as metronidazole may increase its effect. Your doctor may reduce your lithium doses and should monitor your blood levels and kidney function more frequently than normal
- medicine for diabetes such as chlorpropamide, tolbutamide or acarbose as metronidazole may increase the risk of developing severe hypoglycaemia
- medicine for the treatment of cancer, as taking metronidazole in combination with some of these (particularly fluorouracil or busulphan) may increase their adverse effects
- aspirin (used to suppress the immune system), as metronidazole may increase its effect. If your doctor thinks you need both medicines, blood levels and kidney function should be monitored more frequently than normal
- ciclosporin (used to control the effects of excess stomach acid such as ulcers and heartburn), as this may possibly increase the unwanted effects of metronidazole
- the pill (oral contraceptive), as metronidazole may reduce its effectiveness
- disulfiram (used for chronic alcohol dependence), as metronidazole may increase the risk of developing severe behavioural reactions

Dosage in children

Dosage is reduced to 10 mg/kg as a single dose before breast-feeding again.

For babies under 40 weeks old, the dose is reduced to 10 mg/kg as a single dose before the operation.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, to check that the medicine is safe for you to use.

Important information about some of the ingredients of Metronidazole

- If you are to take Metronidazole Tablets for more than 10 days, you may need to have regular blood tests.
- If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if they have the same symptoms as you.
- You should stop taking your tablets if you think they are making you feel unwell. If you think the medicine is not working, or if your infection is getting worse, tell your doctor or pharmacist.
- This medicine may cause dizziness. If you feel dizzy, do not drive or operate any machinery until you know how the tablets will affect you.
- This medicine may cause sleepiness or drowsiness. You should not drive or operate machinery if you feel sleepy.
- Do not use Metronidazole after the expiry date that is stated on the outer packaging. The expiry date is the last day of the month stated.
- Store in a cool, dry place and protect from light. Store in the original package.

WHAT YOU HAVE TO DO WITH ANY LEFTOVER MEDICINE

Do not use Metronidazole Tablets after the expiry date. If you do not finish the course of tablets you have been prescribed, you should ask your pharmacist how to safely dispose of any tablets left over.
The following is a guide to doses for the treatment of other types of infection.

<table>
<thead>
<tr>
<th>Infection</th>
<th>Adults and children over 15 years</th>
<th>Children</th>
<th>Length of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammation of the vagina</td>
<td>400 mg twice a day</td>
<td>Not suitable</td>
<td>5 to 7 days</td>
</tr>
<tr>
<td></td>
<td>or 200 mg as a single dose</td>
<td>1 day</td>
<td></td>
</tr>
<tr>
<td>Infection of the intestinal tract (Amoebiasis)</td>
<td>400 mg three times a day</td>
<td>15 to 30 mg/kg/day, two or three times a day</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>or 200 mg twice a day</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Infection in the pelvic area, brain or wound infections after surgery</td>
<td>200 mg three times a day</td>
<td>100 mg to 300 mg once a day</td>
<td>3 days</td>
</tr>
<tr>
<td></td>
<td>or 500 mg twice a day</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Treatment of infections of the intestinal tract caused by parasitic micro-organisms</td>
<td>400 mg to 600 mg three times a day</td>
<td>100 mg to 300 mg four times a day</td>
<td>5 to 10 days</td>
</tr>
<tr>
<td></td>
<td>or 15 to 40 mg/kg divided into 2 or 3 daily doses</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Treatment of certain bacterial and protozoal infections of the genital tract</td>
<td>1000 mg once a day</td>
<td>600 to 800 mg once a day</td>
<td>3 days</td>
</tr>
<tr>
<td></td>
<td>or 200 mg three times a day</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Possible Side Effects**

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

Stop taking the tablets and tell your doctor immediately if any of the following happens:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or nettle rash).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation. There may be a reduction (sometimes severe) in normal blood cells. If you develop any of the following tell your doctor immediately.

- unexplained bruising or bleeding
- increased frequency or persistent infections especially sore throat
- skin pallor particularly if you also have weakness and/or breathlessness
- increased frequency of severe mouth ulcers.

The following side effects have also been reported:

**Very rare** (less than 1 in 10,000 users):

- increased bleeding, nosebleed, sore throat or infections, this medicine may alter the number and type of your blood cells. You should tell your doctor who might want you to have a blood test
- mental health problems including hallucinations (seeing or hearing things that are not there), drowsiness, dizziess, fatigue, fever or cold symptoms, confusion, feelings of现有的恐惧、Depression, 'pins and needles'
- bone marrow depression disorders such as aplastic anaemia (causing weakness, bruising, making infections more likely)
- jaundice (yellowing of the skin or whites of the eyes), inflammation of the pancreas (pancreatitis causing very severe abdominal pain), flushing
- skin rash, itching, swelling pre-existing conditions, muscles and joint pain, darkening of the urine

**Unlikely** (cannot be estimated from the available data):

- Some mental depression disorders such as anxiolytic agents (causing weakness, bruising, making infections more likely)
- oliguria (the inability to produce urine) in the mouth, dry mouth, changes in taste, fits (seizures), depression, 'pins and needles'
- unpleasant tastes in the mouth, dry mouth, changes in taste, fits (seizures), depression, 'pins and needles'
- skin rash, itching, swelling pre-existing conditions, muscles and joint pain, darkening of the urine

**FURTHER INFORMATION**

**What Metronidazole Tablets contain:**

- The active ingredient is metronidazole 200 mg or 400 mg
- The other ingredients are lactose, maize starch, pregelatinised starch, polyvidone, colloidal silicon dioxide and magnesium stearate.

**What Metronidazole Tablets look like and contents of the pack:**

- Metronidazole 200 mg Tablets are white bisacodyl tablets coded 200, 200 with a breakline on one side, twin triangle logo on the reverse.
- Metronidazole 400 mg Tablets are white bisacodyl tablets coded 400, 400 with a breakline on one side, twin triangle logo on the reverse.
- The 200 mg tablets are available in packs of 10, 14, 15, 20, 21, 26, 30, 50, 60, 100, 250, 500, 1000, 5,000 and 10,000.
- The 400 mg tablets are available in packs of 6, 10, 14, 15, 20, 21, 26, 30, 50, 60, 100, 250, 500 and 1000. Not all pack sizes may be marketed.

**Marketing Authorisation holder and Manufacturer:**

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised: April 2013

**Pharma Code:**

187705
196720
102380
11596-7