**PATIENT INFORMATION LEAFLET**

**Metronidazole 200 mg/5 ml 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, please 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 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 this leaflet for?**

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

**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 - 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).

**2. What you need to know before you take Metronidazole Oral Suspension**

**Do not take Metronidazole Oral Suspension and tell your doctor if:**

- you are allergic (hypersensitive) to metronidazole or any of the ingredients listed below in Section 6. Signs of an allergic reaction include: rash, itching or shortness of breath
- you are pregnant, think you might be pregnant or are breast feeding.

**Warnings and precautions**

**Talk to your doctor, pharmacist or nurse before taking Metronidazole Oral Suspension:**

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

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.

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 Oral Suspension**

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 Oral Suspension can affect the way some other medicines work. Also, some medicines can affect the way Metronidazole Oral Suspension works. In particular, tell your doctor if you are taking any of the following medicines:

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

**Taking Metronidazole Oral Suspension with food and drink**

Do not drink any alcohol while you are taking Metronidazole Oral Suspension and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole Oral Suspension might cause unpleasant side effects such as nausea, vomiting, stomach pain, hot flushes, palpitations and headaches.

**Pregnancy and breast-feeding**

Talk to your doctor before using Metronidazole Oral Suspension if:

- you are pregnant, might become pregnant or think you may be pregnant
- you are breast feeding.

**Driving and using machines**

While taking Metronidazole Oral Suspension you may feel sleepy, dizzy, confused or have a change of vision. This is because Metronidazole Oral Suspension might cause your muscles or brain to work slower than usual. You may feel relaxed and less alert. This can affect your ability to drive or operate machines. If this occurs, do not drive or operate machines.

**Tests**

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

**Important information about some of the ingredients of Metronidazole Oral Suspension**

This product contains:

- Sucrose and sorbitol: 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.
- Methyl hydroxybenzoate: This is a preservative and can cause allergic reactions.

**3. How to take Metronidazole Oral Suspension**

**Taking your medicine**

Always take Metronidazole Oral Suspension exactly as your doctor or pharmacist has told you.

**Taking this medicine**

- This medicine contains 200 mg of metronidazole in each 5 ml.
- Take this medicine by mouth.
- Always shake the bottle before use.
- Complete the full course of this medicine.
- Take this medicine using the measuring spoon provided with Metronidazole Oral Suspension. This spoon is marked in millilitres (ml) to help you measure out the correct amount of this medicine.

**How much to take**

The usual doses for adults and children are:

<table>
<thead>
<tr>
<th>What you are taking the medicine for</th>
<th>Number of days you will take the medicine for</th>
<th>How much to take – Adults and children over 12 years of age</th>
<th>How much to take – Children under 12 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention of infections after surgery</td>
<td>1, 10 ml (400 mg) three times a day on the day before the operation</td>
<td>Your doctor will work out the right dose based on your child’s weight.</td>
<td></td>
</tr>
<tr>
<td>Bacterial infections</td>
<td>A 20 ml (800 mg) dose followed by 10 ml (400 mg) three times a day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Other infections**

**Adults and children over 10 years of age**

<table>
<thead>
<tr>
<th>What you are taking the medicine for</th>
<th>Number of days you will take the medicine for</th>
<th>How much to take – Adults and children over 10 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trichomoniasis</td>
<td>50 ml (2000 mg) once a day</td>
<td></td>
</tr>
<tr>
<td>5 to 7</td>
<td>your doctor or pharmacist will inform you of your dosage.</td>
<td></td>
</tr>
<tr>
<td>Vaginosis</td>
<td>50 ml (2000 mg) once a day</td>
<td></td>
</tr>
<tr>
<td>5 to 7</td>
<td>10 ml (400 mg) twice a day</td>
<td></td>
</tr>
<tr>
<td>Amoebiasis</td>
<td>10 ml (400 mg) to 20 ml (800 mg) three times a day</td>
<td></td>
</tr>
<tr>
<td>Giardiasis</td>
<td>50 ml (2000 mg) once a day</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>10 ml (400 mg) three times a day</td>
<td></td>
</tr>
<tr>
<td>7 to 10</td>
<td>12.5 ml (500 mg) twice a day</td>
<td></td>
</tr>
<tr>
<td>Gingivitis</td>
<td>5 ml (200 mg) three times a day</td>
<td></td>
</tr>
<tr>
<td>Dental infections</td>
<td>5 ml (200 mg) three times a day</td>
<td></td>
</tr>
<tr>
<td>3 to 7</td>
<td>10 ml (400 mg) three times a day</td>
<td></td>
</tr>
</tbody>
</table>
People having kidney dialysis
Kidney dialysis removes Metronidazole Oral Suspension 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 prescribe a lower dose or to use the medicine less often. If you take more Metronidazole Oral Suspension than you should Talk to your doctor or go to the nearest hospital straight away. Take the carton and bottle with you.

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

4. Possible side effects
Like all medicines, Metronidazole Oral Suspension can cause side effects although not everybody gets them.

Tell your doctor or pharmacist straight away if you notice any of the following side effects:

- Loss of appetite, anorexia
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain
- Furred tongue, dry mouth
- Unpleasant taste in the mouth
- Fever
- Pains in the muscles or joints
- Feeling sleepy or dizzy
- Faintness, tingling, pain or a feeling of weakness in the arms or legs
- Diarrhoea
- Feeling sleepy or dizzy
- Pains in the muscles or joints
- Numbness, tingling, pain or a feeling of weakness in the arms or legs
- Fever
- Unpleasant taste in the mouth
- Furred tongue, dry mouth
- Feeling sick (nausea), being sick (vomiting), upset stomach, stomach pain or diarrhoea
- Loss of appetite, anorexia
- Depression.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the UK: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Metronidazole Oral Suspension
Keep out of the sight and reach of children.

- Do not store above 25°C.
- Store your medicine in the original packaging in order to protect them from light.
- Once opened: Use within 12 weeks
- Do not use this medicine after the expiry date shown on the bottle label and packaging. The expiry date refers to the last day of that month.
- 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. Contents of the pack and other information

What Metronidazole Oral Suspension contains
Each 5 ml of oral suspension contains metronidazole benzate equivalent to 200 mg of metronidazole.

Other ingredients are:
- Microcrystalline cellulose and carmellose sodium (90:10), croscarmellose sodium (E468), sucrose, sorbitol 70% (E420), sodium saccharin (E954), polysorbate 80 (E433), propylene glycol (E1520), colloidal anhydrous silica, sodium dihydrogen phosphate dihydrate (E339) (for pH adjustment), sodium citrate dihydrate (E331) (for pH adjustment), methyl parahydroxybenzoate (E218), lemon flavour, orange flavour and purified water.

What Metronidazole Oral Suspension looks like and contents of the pack
The suspension is white to cream-coloured having a sweet taste and an orange-temon flavour. It is available in 100 ml amber coloured glass bottles with a white polypropylene cap.

Marketing Authorisation Holder
DAWA Limited, 5 Sandridge Close, Harrow, Middlesex HA1 1XD, UK
Manufacturer
Drugsrus Limited, 5 Sandridge Close, Harrow, Middlesex HA1 1XD, UK

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