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 pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. What Metronidazole tablets are and what they are used for

Metronidazole tablets belong to a group of medicines called anti-infective agents. They may be used to treat:
- infections, caused by bacteria of the blood, brain, bone, lung, stomach lining and pelvic area, following childbirth or in a wound following an operation
- urinary or genital infections caused by a parasite, Trichomonas
- genital infection in women caused by bacteria
- the diarrheic diseases
- the disease giardiasis
- gum and teeth infections
- infected leg ulcers or pressure sores
- stomach ulcers caused by Helicobacter pylori.
- or prevent infections occurring after operations.

2. Before you take

Do not take Metronidazole tablets and tell your doctor if you:
- are allergic (hypersensitive) to Metronidazole tablets or any of the other ingredients (see section 6)
- are in the first 3 months of pregnancy or are breastfeeding
- are in the 4th-9th month of pregnancy
- are taking other medicines (see section 3)
- have disorders of the nervous system, particularly if you require dialysis treatments
- have ever had liver disease
- are in the 4th-9th month of pregnancy
- have epilepsy or have ever had fits
- have porphyria (a genetic disease that can cause skin blisters, abdominal pain and brain/nervous system disorders)
- have any disorder of the blood and/or blood cells
- have any nervous system disorders
- have been exposed to any sexually transmitted disease.

Check with your doctor or pharmacist before taking Metronidazole tablets if you:
- have kidney disease, particularly if you require dialysis treatments
- are or have ever suffered from any liver disease
- are in the 4th-9th month of pregnancy
- have epilepsy or have ever had fits
- have porphyria (a genetic disease that can cause skin blisters, abdominal pain and brain/nervous system disorders)
- have any disorder of the blood and/or blood cells
- have any nervous system disorders
- have been exposed to any sexually transmitted disease.

3. How to take

Follow your doctor or pharmacist’s instructions carefully. The usual dosage is:

Children 8 weeks-12 years: 20-30mg/kg/day as a single divided dose.

- 20mg/kg/day for the first 3 days then 15mg/kg/day for the rest of the treatment.
- 10mg/kg/day if you are also taking an antibiotic (metronidazole is used to treat infections caused by bacteria and an antibiotic is used to treat infections caused by bacteria and fungi).

Doses:
- Treatment of bacterial infections
  - Adults and children over 10 years: 800mg followed by 400mg at eight hourly intervals. Treatment is usually for 7 days but will depend upon your condition.
  - Treatment of anaerobic infections
  - Children 8 weeks-12 years: 20-30mg/kg/day as a single dose or divided into 7.5mg/kg every 8 hours for 7 days.
  - Children under 8 weeks: 15mg/kg/day as a single dose or divided into 7.5mg/kg every 12 hours.

Metronidazole tablets may make you feel drowsy, dizzy, confused or affect your vision, cause fits or hallucinations. Make sure you are not affected before you drive, operate machinery or take part in any activities where these may put you or others at risk.

4. Possible side effects

If you have been told you have an intolerance to sugar, contact your doctor before taking this medicine, as it contains a sugar called lactose.

Tests
- If you are taking this medicine for more than 10 days, your doctor may wish to carry out further tests.
- If you need any blood or urine tests, tell your doctor you are taking Metronidazole tablets before the test.

5. How to store

- Keep this medicine in a cool dry place.
- Do not store above 25°C.
- Do not freeze.
- Protect from light.

6. Further information

Sugar intolerance
- If you have diabetes, please consult with your doctor or pharmacist before taking this medicine.
- If you are on a diet to control your blood sugar levels, please consult with your doctor or pharmacist before taking this medicine.

Driving and using machines
- Metronidazole tablets may make you feel drowsy, dizzy, confused or affect your vision, cause fits or hallucinations. Make sure you are not affected before you drive, operate machinery or take part in any activities where these may put you or others at risk.

Other medicines
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:
  - medicines to stop the blood clotting such as warfarin, lithium (used to treat depression)
  - medicines to treat epilepsy such as phenobarbital, phenytoin, primidone
  - diuretics (to treat alcohol addiction)
  - acitretin (used following organ transplants)
  - fluoroquinolones (used to treat some forms of cancer)
  - diethylene, used to treat stomach ulcers
  - oestrogen contraceptives (‘the pill’).

Pregnancy and breastfeeding
- Metronidazole tablets must not be taken during the first 3 months of pregnancy and should not be taken during the rest of the pregnancy.
- If you breastfeed you should stop whilst taking Metronidazole tablets and for 12-24 hours after the course of tablets has finished before breastfeeding again.
- Ask your doctor or pharmacist for advice before taking this medicine.

Metronidazole 200mg and 400mg Tablets

Index
1. What Metronidazole tablets are and what they are used for
2. Before you take
3. How to take
4. Possible side effects
5. How to store
6. Further information

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Metronidazole 200mg and 400mg tablets 21pk PIL - UK

Contact your doctor at once if you notice any of the following side effects:
- Allergic reactions: skin rash, which may be itchy, swelling of the face, lips, tongue or throat, fever or difficulty in breathing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Very rare (less than 1 in 10,000 users):
- increased bruising, nosebleeds, sore throats or infections, this medicine may alter the numbers and types 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), dizziness, dizziness, fits, tingling, pain or a feeling of weakness in the arms or legs, numbness.
- menopausal headache (headache, sensitivity, confusion, fever, paralysis, stiff neck).
- cerebellar syndrome (poor co-ordination or muscle control, involuntary shaking, uncontrolled eye movements, speech disorders, walking abnormally).
- double vision, short sightedness.
- change in liver function tests, jaundice (yellowing of the skin or whites of the eyes), inflammation of the pancreas (pancreatitis causing very severe abdominal pain), flushing.
- skin rash, itching, small pus-containing blisters, muscles and joint pain, darkening of the urine.

Not known (cannot be estimated from the available data):
- bone marrow depression disorders such as aplastic anaemia (causing weakness, bruising, making infections more likely).
- Urticaria (itchy, pale or red irregular raised patches of skin), fever.
- depression, ‘pins and needles’.
- unpleasant taste in the mouth, changes in taste, furred tongue, mouth ulcers, feeling or being sick, loss of appetite, diarrhoea, stomach pain and upset stomach.
- erythema multiforme (red, red patches).
- If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

How to store
Keep out of the reach and sight of children.
Store below 25°C in a dry place.
Do not use Metronidazole tablets after the expiry date stated on the label/carton/bottle. 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.

What Metronidazole tablets look like and contents of the pack
Metronidazole 200mg tablets are white, film-coated tablets.
Metronidazole 400mg tablets are white, capsule shaped, biconvex, film-coated tablets.
Pack sizes are 21 tablets.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstable, EX2 8NS, UK.
Date of last revision: March 2012

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The active substance (the ingredient that makes the tablets work) is metronidazole.
- The other ingredients are croscarmellose sodium, cellulose, colloidal silica, lactose, magnesium stearate, maize starch, polyethylene glycol, titanium dioxide (E171), hydroxypropylcellulose (E463), methylhydroxypropylcellulose (E464).

What Metronidazole tablets contain

What Metronidazole tablets tell you about the ingredients

Metronidazole 200mg and 400mg tablets 21pk PIL - UK

Possible side effects
Like all medicines, Metronidazole tablets can cause side effects, particularly when you first start taking it, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

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