

Sandoz Ltd	December 2016
Metrolyl (Metronidazole) Tablets 200mg and 400mg	PL 04416/0060 & 0061

PATIENT INFORMATION LEAFLET

METROLYL® (METRONIDAZOLE) TABLETS BP 200mg AND 400mg

What you should know about Metrolyl®

Please read this carefully before you start to take your medicine. This leaflet provides a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

The name of your medicine is Metrolyl® (Metronidazole) Tablets BP 200mg or 400mg.

What is in your Medicine?

Each tablet contains 200mg or 400mg of the active ingredient metronidazole BP. They also contain: lactose, microcrystalline cellulose, magnesium stearate and maize starch. The 200mg tablets also contain gelatin and the 400mg tablets also contain povidone.

The 200mg tablets are supplied in packs of 14, 21 and 250 and the 400mg tablets are supplied in packs of 14, 21 and 100.

The active ingredient, metronidazole, is an antibacterial agent used to treat infections.

The product licence holder and manufacturer is: Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom.

Uses

Metrolyl® (Metronidazole) Tablets are used to treat different types of infections which are due to particular types of bacteria and some other infectious organisms, or to prevent infection during an operation.

Before taking your Medicine

DO NOT take this medicine before telling your doctor if:

- you are, or might be, pregnant or you are breast-feeding
- you have experienced sensitivity to metronidazole, or any of the other ingredients in this medicine
- you have liver disease

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.

It is very important that you tell your doctor if you are taking any other medication particularly phenobarbitone (used for epilepsy and convulsions), anticoagulants such as warfarin (used to prevent blood clots), lithium (used to treat depressive illness); or any other medication you have obtained without a prescription.

Do not drink alcohol while taking metronidazole as you may get an unpleasant reaction.

You should not drive, operate machinery or carry out other activities requiring full alertness if you experience any dizziness or drowsiness while taking this medicine.

If you have kidney failure and have dialysis while you are taking metronidazole, your doctor may alter the timing of your next dose.

Metronidazole therapy may affect tests for liver function.

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Taking your Medicine

Recommended doses follow. Doctors sometimes prescribe different doses to these: if this applies to you, discuss it with the doctor, if you have not already done so. You should always follow your doctor's instructions as to when and how to take your medicine. Your pharmacist may be able to advise if you are not sure. Exactly how many tablets and when to take them will be written on the label. Please read it carefully.

Treatment with metronidazole will normally be for 7 days. Shorter or longer treatment may be prescribed if your doctor feels this is necessary. If treatment is to continue for longer than 10 days your doctor will keep a close eye on you. You should continue and complete the course of metronidazole prescribed for you even if you are feeling better.

Metrolyl® (Metronidazole) Tablets should be swallowed with a drink of water during or after a meal.

The normal daily doses are as follows.

For the treatment of infections

Metronidazole Tablets may be given on their own or with other medicines which kill bacteria.

General dosage

<u>Adults:</u>	400mg, 3 times a day.
<u>Children 8 weeks to 12 years:</u>	20-30mg of metronidazole for each kilogram of the child's body weight a day <u>or</u> 7.5mg of metronidazole for each kilogram of the child's weight every 8 hours, for 7 days
<u>Children under 8 weeks:</u>	15mg of metronidazole for each kilogram of the child's body weight a day <u>or</u> 7.5mg of metronidazole for each kilogram of the child's body weight every 12 hours.

If you have liver problems, your dose may be reduced to one-third of the normal dosage, once a day.

For patients with urogenital infections

Sexual partners should be treated concurrently.

<u>Adults and children over 10 years:</u>	200mg, 3 times a day for 7 days <u>or</u> 400mg twice a day for 5-7 days, <u>or</u> 2,000mg once.
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<u>Children under 10 years:</u>	40mg of metronidazole for each kilogram of the child's body weight once <u>or</u> 15-30mg of metronidazole for each kilogram of the child's body weight, in 2-3 doses, for 7 days.
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In bacterial infections of the vagina

<u>Adults and children over 10 years:</u>	400mg twice a day for 5-7 days <u>or</u> 2,000mg once as a single dose.
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Dysentery/amoebiasis: invasive intestinal disease

<u>Adults and children over 10 years:</u>	800mg, 3 times a day for 5 days.
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<u>Children:</u>	7 to 10 years:	400mg, 3 times a day for 5 days.
	3 to 7 years:	200mg, 4 times a day for 5 days.
	1 to 3 years:	200mg, 3 times a day for 5 days.

Dysentery/amoebiasis: intestinal disease and chronic amoebic hepatitis

<u>Adults and children over 10 years:</u>	400mg, 3 times a day for 5 to 10 days.
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<u>Children:</u>	7 to 10 years:	200mg, 3 times a day for 5 to 10 days.
	3 to 7 years:	100mg, 4 times a day for 5 to 10 days.
	1 to 3 years:	100mg, 3 times a day for 5 to 10 days.

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Dysentery/amoebiasis: amoebic liver abscess and other forms of extra-intestinal amoebiasis

Adults and children over 10 years: 400mg, 3 times a day for 5 days.

Children:

7 to 10 years:	200mg, 3 times a day for 5 days.
3 to 7 years:	100mg, 4 times a day for 5 days.
1 to 3 years:	100mg, 3 times a day for 5 days.

Dysentery/amoebiasis: in patients who have passed cysts but who are otherwise symptomless

Adults and children over 10 years: 400mg to 800mg, 3 times a day for 5 to 10 days.

Children:

7 to 10 years:	200mg to 400mg, 3 times a day for 5 to 10 days.
3 to 7 years:	100mg to 200mg, 4 times a day for 5 to 10 days.
1 to 3 years:	100mg to 200mg, 3 times a day for 5 to 10 days.

For giardiasis

Adults and children over 10 years: 2,000mg, once a day for 3 days, or 400mg 3 times a day for 5 days, or 500mg twice a day for 7-10 days.

Children:

7 to 10 years:	1,000mg, once a day for 3 days.
3 to 7 years:	600mg to 800mg, once a day for 3 days.
1 to 3 years:	500mg, once a day for 3 days.

For gum disease (acute ulcerative gingivitis)

Adults and children over 10 years: 200mg, 3 times a day for 3 days.

Children:

7 to 10 years:	100mg, 3 times a day for 3 days.
3 to 7 years:	100mg, twice a day for 3 days.
1 to 3 years:	50mg, three times a day for 3 days.

For acute dental infections

Adults and children over 10 years: 200mg, 3 times a day for 3 to 7 days.

For leg ulcers and pressure sores

Adults and children over 10 years: 400mg, 3 times a day for 7 days.

For the treatment of *H.pylori* infections

Children: 20mg of metronidazole a day for each kilogram of the child's body weight for 7-14 days.

For the prevention of infections

In gynaecological surgery

Adults and children over 12 years: 1,000mg as a single dose, followed by 200mg, 3 times a day until pre-operative withholding of solids and liquids by mouth becomes necessary. 200mg, 3 times a day should be resumed after the operation and for a period of up to 7 days.

Children under 12 years: 20-30mg of metronidazole for each kilogram of the child's body weight 1-2 hours before surgery.

Newborns: 10mg of metronidazole for each kilogram of the child's body weight before surgery.

As a pre-operative medication prior to surgery on your colon

Adults and children over 12 years: 200mg every 6 hours, with an aminoglycoside antibiotic for 3 days before surgery

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or

400mg every 8 hours with phthalylsulphathiazole (2,500mg every 6 hours) for 4 days before your operation.

Children under 12 years: 20-30mg of metronidazole for each kilogram of the child's body weight 1-2 hours before surgery.

Newborns: 10mg of metronidazole for each kilogram of the child's body weight before surgery.

If you forget to have a dose, take the missed dose as soon as you remember. If your next dose is due within 2 hours, have a single dose straight away and skip the next.

If you take an unintentional extra dose, this should not cause problems. If you or someone else has taken too many tablets or a large overdose has been taken, seek medical help immediately.

As with all medicines, metronidazole may cause unwanted effects in some people, although serious reactions are rare. An unpleasant taste in the mouth, furred tongue, nausea, vomiting or other gastro-intestinal disturbance has been reported.

Occasionally, you may feel drowsy, dizzy, have a headache and feel shaky or unsteady while taking metronidazole.

Hypersensitivity reaction can occur including skin rashes, including nettle rash, or itching. Rarely, a more severe allergic reaction can occur called angioedema, symptoms of which are large, well-defined swellings which suddenly occur in the skin, particularly around the face and throat. Extremely rarely, a very severe allergic reaction called anaphylaxis may occur. Symptoms of this may be lowered blood pressure (making you feel dizzy or light-headed), itchy raised rash, tightness in the chest and breathing difficulties, swelling of the tongue or throat, pain in the stomach and diarrhoea. If any of these rare reactions occur, contact your hospital accident and emergency department immediately.

Peripheral neuropathy (a disease of the peripheral nerves, symptoms of which are general weakness and numbness) and/or convulsions or fits have occurred during prolonged or intensive treatment with metronidazole. In most cases peripheral neuropathy disappears when treatment is stopped.

Changes to your blood may occur (red cells, white cells, platelets, etc). If there is a tendency to bruise easily, you notice bleeding into the skin, prolonged bleeding, bleeding from the gums or elsewhere, or you feel tired and look pale, stop taking the medicine and see your doctor.

Rarely patients may develop liver disease and jaundice (yellowing of the skin and the whites of the eyes), or darkening of the urine.

If you have any of these effects and they become worse, inconvenient or upsetting; see your doctor or pharmacist. If you experience any other unpleasant effects which you think could be caused by this medicine you should contact your doctor or pharmacist for advice.

Storing your Medicine

Do not use Metrolyl® (Metronidazole) Tablets BP 200mg or 400mg after the expiry date shown on the label. Any out of date medicines should be returned to your pharmacist for disposal.

Do not store above 25°C. Store in the original container.

If you notice any defects in the tablets, such as chips or broken tablets, take them to your pharmacist for advice before taking them.

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Keep all medicines out of the reach and sight of children. Your medicines can harm them.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others it may harm them even if their symptoms are the same as yours.

This leaflet only applies to Metrolyl[®] (Metronidazole) Tablets BP 200mg or 400mg.

[®] trade mark

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