

Flazon 125 mg/5ml

Pharmaceutical form: Oral suspension.

Composition: The active ingredient is metronidazole benzoate.

Excipients: Sucrose, Glycerol, Propylene glycol, Polysorbate 80, Xanthan Gum, Microcrystalline cellulose, Methylparaben, Propylparaben, Banana flavour liquid, Purified water.

Indications:

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. This is 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 (1-12 year)

It can also be used in children to treat a bacterial infection in the stomach (*Helicobacter pylori*)

Newborns

(full term) It can be used in full term newborns for treating bacterial infections and preventing infections after an operation

Before you take Flazon Do not take Flazon and tell your doctor if:

- you are allergic (hypersensitive) to metronidazole or any other ingredients in this liquid (listed below). Signs of an allergic reaction include a rash, itching or shortness of breath
- you are pregnant; think you are pregnant or breast feeding.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you are patient with diabetes mellitus.

Take special care with Flazon Before you take Flazon, tell your doctor if:

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

If you are on this medicine for more than 10 days, your doctor may give you some tests.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Flazon.

Taking other medicines

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 Flazon can affect the way some other medicines work. Also, some medicines can affect the way Flazon works.

In particular, tell your doctor if you are taking any of the following:

- warfarin - used to thin your blood
- lithium - used to treat depression
- phenobarbital - used to treat epilepsy
- 5-fluorouracil - used to treat cancer
- busulfan – used to treat leukaemia
- ciclosporine - used after organ transplants.

Taking Flazon with food and drink

Do not drink alcohol whilst taking Flazon and for 48 hours after finishing the treatment. Drinking alcohol may cause unpleasant side effects such as nausea, vomiting, pain in and around your stomach area (the abdomen), hot flushes, palpitations and headaches.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine. You should not take Flazon if you are pregnant, planning to become pregnant or are breast-feeding.

Important information about what is in Flazon

- Each 5ml contains 1.800 g sucrose/saccharose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The saccharose content should be taken into account in patients with diabetes mellitus. It may also be harmful to teeth.
- methyl and propyl parabens. These may cause an allergic reaction possibly delayed.
- glycerol, which can be harmful in high doses and can use cause headache, stomach upset and diarrhoea.

How to take Flazon

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure. The different routines you might follow are shown below.

Taking this medicine

- This medicine contains 125mg of metronidazole in each 5ml
- Take this medicine by mouth
- Always shake the bottle before use
- Complete the full course of this medicine.

How much to take

The usual doses for adults and children are:

Prevention of infections after surgery

Number of days you will take the medicine for: 1

How much to take – Adult and children over 12 years of age: 16 ml (400mg) three times during the day before the operation

How much to take – Children under 12 years of age: Your doctor will work out the right dose on your child's weight

Bacterial infections

Number of days you will take medicine for: -

How much to take – Adults and children over 12 years of age: A 32 ml (800mg) dose followed by 400mg (16 ml) three times a day

How much to take – Children under 12 years of age: Your doctor will work out the right dose based on your child's weight

Other infections

Adults and children over 10 years of age

Trichomoniasis

Number of days you will take the medicine for: 1

How much to take: 80 ml (2000mg) once a day

Number of days you will take the medicine for: 5 to 7

How much to take: 16 ml (400mg) twice a day

Number of days you will take the medicine for: 7

How much to take: 8 ml (200mg) three times a day

Vaginosis

Number of days you will take the medicine for: 1

How much to take: 80 ml (2000mg) once a day

Number of days you will take the medicine for: 5 to 7

How much to take: 16 ml (400mg) twice a day

Amoebiasis

Number of days you will take the medicine for: 5 to 10

How much to take: 16 ml (400mg) to 32 ml (800mg) three times a day

Giardiasis

Number of days you will take the medicine for: 3

How much to take: 80 ml (2000mg) once a day

Number of days you will take the medicine for: 5

How much to take: 16 ml (400mg) three times a day

Number of days you will take the medicine for: 7 to 10

How much to take: 20 ml (500mg) twice a day

Gingivitis

Number of days you will take the medicine for: 3

How much to take: 5ml (200mg) three times a day

Dental infections

Number of days you will take the medicine for: 3 to 7

How much to take: 5 ml (200mg) three times a day

Leg ulcers and pressure sores

Number of days you will take the medicine for: 7

How much to take: 16 ml (400mg) three times a day

Children under 10 years of age

Trichomoniasis

Number of days you will take the medicine for: 7

How much to take. Children aged 7-10 years: Your doctor will work out the right dose based on your child's weight.

This should not exceed 2000mg a day.

How much to take. Children aged 3-7 years: Your doctor will work out the right dose based on your child's weight.

This should not exceed 2000mg a day.

How much to take. Children aged 1-3 years: Your doctor will work out the right dose based on your child's weight.

This should not exceed 2000mg a day

Amoebiasis

Number of days you will take the medicine for: 5 to 10

How much to take – Children aged 7-10 years: 8 ml (200mg) to 16 ml (400mg) three times a day

How much to take – Children aged 3-7 years: 4 ml (100mg) to 8 ml (200mg) four times a day

How much to take – Children aged 1-3 years: 4 ml (100mg) to 8 ml (200mg) three times a day

Your doctor will work out the right dose based on your child's weight. This should not exceed 2400mg a day

Giardiasis

Number of days you will take the medicine for: 3

How much to take – Children aged 7-10 years: 40 ml (1000mg) once a day

How much to take – Children aged 3-7 years: 24 ml(600mg) to 32 ml (800mg) once a day

How much to take – Children aged 1-3 years: 20 ml (500mg) once a day

Your doctor will work out the dose based on your child's weight

Gingivitis

Number of days you will take the medicine for: 3

How much to take – Children aged 7-10 years: 4 ml (100 mg) three times a day

How much to take – Children aged 3-7 years: 4 ml (100 mg) twice a day

How much to take – Children aged 1-3 years: 2 ml (50mg) three times a day

Children – treatment for a bacterial infection in the stomach (*Helicobacter pylori*)

Your child will be given Flazon with other medicines. Your doctor will work out the right dose based on your child's weight. This should not exceed 500mg twice a day

Older people and those with liver problems

Your doctor may prescribe a lower dose than that given to adults. This is because you may be more sensitive to the medicine.

If you take more Flazon than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Flazon

Do not take a double dose (two doses at the same time) to make up for a forgotten dose. Take your next dose as soon as you remember, then go on as before. However, if it is nearly time for the next dose, skip the missed dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

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

If you have an allergic reaction to Flazon, see a doctor straight away

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

If you get any of the following side effects, stop taking Flazon and see your doctor as soon as possible:

- fits (convulsions)
- pain and swelling of your skin or skin rashes
- severe pain in and around your stomach area (the abdomen)
- yellowing of your skin and the whites of your eyes (jaundice)
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness
- drowsiness and dizziness
- clumsiness or poor co-ordination
- temporary affects on your eyesight, such as difficulty in focusing
- numbness, tingling, pain or feeling weak in your arms and legs
- feeling confused
- seeing or hearing things that are not there (hallucinations).

Tell your doctor if you get any of these side effects:

- feeling or being sick, upset stomach or diarrhoea
- unpleasant taste in your mouth or a furry tongue
- loss of appetite
- itching
- headache
- darkening of your urine
- pains in your joints or muscles.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

How to store Flazon

- Keep out of reach of children
- Should be protected from light and stored at the temperature below 25°C
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year)
- The shelf life of Flazon is 36 months
- The expiry date refers to the last day of that month
- Do not use Flazon if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist