

Package leaflet: Information for the patient
Metronidazole 5mg/ml solution for infusion
Metronidazole

Read all of this leaflet carefully before you start using 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, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Metronidazole 5mg/ml is and what it is used for

Metronidazole 5mg/ml belongs to a group of medicines known as antibiotics and is used to treat severe infections caused by bacteria that can be killed by the active substance metronidazole.

In general this medicine is suitable for adults, adolescents, children and newborns. Your doctor will decide if the solution is suitable for your individual situation.

You may be given Metronidazole 5mg/ml for the treatment of any of the following diseases:

- infections of the central nervous system such as abscesses (local infection with pus) in the brain, inflammation of the meninges (lining of brain)
- infections of the lungs and lung lining, such as pneumonia accompanied by tissue destruction, pneumonia following entry of stomach contents into the lungs, abscesses in the lungs,
- infections of the gastro-intestinal tract, such as inflammation of the internal lining of the abdomen and pelvic walls, abscesses in the liver, large bowel or rectal surgery, infections with pus in the abdomen and pelvis,
- infections of the female sex organs, such as inflammation within the womb, after removal of the womb, caesarean section, miscarriage accompanied by blood poisoning (sepsis), infection of the womb following childbirth.
- infections of the ears, nose and throat, and teeth, jaw and mouth, such as serious gum infection
- inflammation of the inner lining of the heart
- bone and joint infections, such as inflammation of the bone marrow
an infection that produces gas in tissues where there is gangrene
- blood infection (or poisoning) arising from a clot and inflamed veins

If required, your treatment may be supplemented by other antibiotics.

Metronidazole 5mg/ml may be given as a preventive measure prior to operations associated with a higher risk of infection with what are known as anaerobic bacteria, mainly in gynaecology or surgery on stomach and gut.

2. What you need to know before you use Metronidazole 5mg/ml

Do not use Metronidazole 5mg/ml

- if you are allergic to metronidazole, other similar substances or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before receiving Metronidazole 5 mg/ml.

Take special care with Metronidazole 5mg/ml if you have:

- severe liver damage,
- a blood formation disorder or
- a disease of brain, spinal cord or nerves.

Therefore, your doctor will very carefully determine whether you should be treated with Metronidazole 5mg/ml.

If convulsive fits or any other nerve problems or symptoms (e.g. numbness in limbs) become apparent during therapy, your treatment will promptly be revised.

Treatment with Metronidazole 5 mg/ml should not usually be continued for longer than 10 days; the treatment period will only be extended in exceptional circumstances and if absolutely necessary. Repeat therapy with metronidazole will be restricted to cases where this is absolutely necessary. In such a case, you will be monitored particularly carefully.

Especially with prolonged metronidazole treatment or if you are immunocompromised, an imbalance of the intestinal flora may occur.

Treatment must be stopped or revised immediately if you get severe diarrhoea which may be due to a severe large bowel disease called “pseudomembranous colitis” (see also section 4.)

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.
- Serious reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with Metronidazole 5 mg/ml treatment. Stop using Metronidazole 5 mg/ml and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

As prolonged use of metronidazole may impair blood formation (see section “Possible side effects”), your blood counts will be monitored during treatment.

Other medicines and Metronidazole 5 mg/ml

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Medicines that may cause heart rhythm disturbances

Tell your doctor if you are taking any medicines that can cause a heart rhythm disorder (the so-called QT interval prolongation that can be seen on an ECG), such as certain antiarrhythmics (medicines to treat heart rhythm disorders like e.g., amiodarone) and certain antibiotics (like e.g., ciprofloxacin).

When you receive these medicines, your heart function should be monitored. You should see your doctor if you notice any heart function abnormalities, dizziness or fainting.

Barbiturates (an active substance in medicines to treat epilepsy or seizures)

The duration of action of metronidazole is reduced by phenobarbital; your metronidazole dose may therefore have to be increased.

Busulfan

Metronidazole should not be given to patients receiving busulfan because in that case toxic effects are more likely to occur.

Carbamazepine (a drug for the treatment of epilepsy)

This combination also warrants caution because metronidazole may increase the duration of action of carbamazepine.

Cimetidine (a drug for the treatment of stomach disorders)

Cimetidine may reduce the elimination of metronidazole in isolated cases and subsequently leads to increased serum metronidazole concentrations.

Coumarin derivatives (drugs that inhibit blood clotting)

Metronidazole may enhance the blood clotting inhibition brought about by coumarins. So if you are taking a medicine that inhibits blood clotting (for example warfarin), you may need less of it during treatment with metronidazole.

Cyclosporin (a drug used to suppress undesirable immune responses)

When cyclosporin is given together with metronidazole, the blood levels of cyclosporin may increase; your doctor will therefore have to adjust your cyclosporin dose as appropriate. In addition your kidney function will be monitored.

Disulfiram (used in alcohol withdrawal therapy)

If you are taking disulfiram, you must not be given metronidazole, or disulfiram must be stopped. Combined use of these two drugs may lead to states of confusion up to the point of a serious mental disorder (psychosis).

Fluorouracil (an anticancer drug)

The daily dose of Fluorouracil may have to be reduced when giving it together with Metronidazole because metronidazole may lead to an increase of the blood level of Fluorouracil.

Lithium (used to treat mental illness)

Treatment with lithium preparations requires particularly careful monitoring during treatment with metronidazole, and the dose of the lithium preparation may need to be re-adjusted.

Mycophenolate mofetil (used for the prevention of rejection reactions after organ transplant)

Its effect may be weakened by metronidazole, so careful monitoring of the effect of mycophenolate mofetil is recommended.

Phenytoin (a drug for the treatment of epilepsy)

If you are taking phenytoin, your doctor will treat you with metronidazole only with caution because metronidazole may increase the duration of action of phenytoin. On the other hand, phenytoin may reduce the effect of metronidazole.

Tacrolimus (used to suppress unwanted immune reactions)

The blood levels of this agent and your kidney function should be checked when starting and stopping treatment with metronidazole.

Metronidazole 5 mg/ml with alcohol

You must not drink any alcoholic beverages while you are being given metronidazole and for 48 hours after finishing your course. Drinking alcohol while using Metronidazole 5 mg/ml may cause you to feel very unwell with symptoms such as palpitations, flushing, sweating, dizziness and vomiting.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine

Pregnancy

If you are pregnant, your doctor will not treat you with metronidazole unless she/he considers this absolutely necessary.

Breast-feeding

You should not breast-feed during treatment with metronidazole and not resume nursing for another 2–3 days thereafter because metronidazole passes into breast milk.

Fertility

Some animal studies did suggest a possible negative effect of metronidazole on the male fertility, but this was only with doses much higher than is recommended for humans.

Driving and using machines

You should not drive or use any machines while being treated with metronidazole as metronidazole may impair alertness. This is even more the case at the beginning of treatment or when you have drunk alcohol.

Metronidazole 5mg/ml contains sodium

This medicine contains 322 mg sodium (main component of cooking/table salt) in each 100 ml. This is equivalent to 16% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Metronidazole 5mg/ml

Dosage

Dosage depends on the nature and severity of your illness, your age and body weight, and your

individual response to treatment.

The following dosages are usually prescribed:

Adults and adolescents over 12 years

Treatment of infections:

Usually you will be given 300 ml of the medicine (corresponding to 1500 mg of metronidazole) on the first day of treatment.

From the second day of treatment onwards you will receive 200 ml of the medicine (corresponding to 1000 mg of metronidazole) every day.

As an alternative you may receive 100 ml of the medicine (corresponding to 500 mg of metronidazole) every 8 hours.

At the beginning of your treatment your doctor may give you an initial higher dose of metronidazole.

In most cases treatment will take 7 days. Only exceptionally treatment may be continued beyond this time.

The dose is usually the same for patients with kidney disease. However if you are receiving dialysis treatment, your doctor may adapt your dose on the days of your treatment.

For patients with liver diseases, lower doses may be required.

Prevention of infections that might occur after operations

When used for prevention of infection in surgery, you may be given 500 mg of the medicine before the operation. The dose will be repeated 8 and 16 hours after the operation.

Use in children

Dosing in children is based on body weight.

Treatment of infections:

Age Dosage

8 weeks to 12 years

20 – 30 mg of metronidazole per kg body weight per day as a single dose
or 7.5 mg of metronidazole per kg body weight every 8 hours.

The daily dose may be increased to 40 mg of metronidazole per kg body weight if infection is severe.

Under 8 weeks

15 mg of metronidazole per kg body weight as a single dose daily or 7.5 mg per kg BW every 12 hours.

Newborns of less than 40 weeks gestation age

As metronidazole may accumulate in these patients during the first week of life, the concentration of metronidazole in the blood will be checked after a few days of treatment

Usually treatment will take 7 days.

Prevention of infections that might occur after operations:

Age Dosage

Less than 12 years

20 – 30 mg of metronidazole per kg body weight as a single dose given 1 –2 hours before surgery

Newborns of less than 40 weeks gestation age

10 mg of metronidazole per kg body weight as a single dose before surgery

Method of administration and duration of treatment

Metronidazole 5mg/ml is administered through a drip directly into a vein (intravenous infusion).

The infusion of one bottle usually takes 60 minutes, but it should not be done within less than 20 minutes.

This medicine may be diluted in a suitable solution for infusion.

The entire metronidazole treatment period is usually 7 days and must not exceed 10 days. It will only be extended in exceptional circumstances and if absolutely necessary. If you are concurrently receiving other antibiotics your doctor will give you those medicines separately.

If you use more Metronidazole 5mg/ml than you should

Undesirable effects, as described in the next section, may occur as signs or symptoms of an overdose.

There is no known specific antidote or specific treatment of a massive overdose, but metronidazole can be removed by dialysis (that is treatment with artificial kidney) from the body.

4. Possible side effects

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

Side effects occur mostly at high doses or with prolonged use.

The following terms are used to describe the frequency of side effects:

‘very common’ affects more than 1 of 10 treated patients

‘common’ affects 1 to 10 of 100 treated patients

‘uncommon’ affects 1 to 10 of 1,000 treated patients

‘rare’ affects 1 to 10 of 10,000 treated patients

‘very rare’ affects less than 1 of 10,000 treated patients

‘not known’ frequency cannot be estimated from the available data

Stop using Metronidazole 5 mg/ml and seek medical attention immediately if you notice any of the following symptoms:

Rare:

- Severe persistent diarrhoea (possibly a symptom of a severe bowel infection called pseudomembranous colitis)

Emergency management of pseudomembranous enterocolitis

In the event of severe persistent diarrhoea, you must promptly inform your doctor because this may be due to pseudomembranous colitis, a serious condition that must be treated immediately. Your doctor will stop metronidazole and provide appropriate treatment.

- Severe acute hypersensitivity reactions up to allergic shock (swelling of the face, lips and airways well as low blood pressure, shortness of breath, collapse and even death)

Very rare:

- White blood cells and platelet counts may decrease during treatment (granulocytopenia, agranulocytosis, pancytopenia, thrombocytopenia). Regular monitoring of blood cell counts is necessary during prolonged use.
- Hepatitis (liver inflammation), jaundice, inflammation of the pancreas (isolated reports)
- Brain disorders, lack of coordination

Not known:

- Mild to moderate hypersensitivity reactions, a special kind of rapid swelling of the skin of your face called angioedema
- Gaze spasm, damage or inflammation of the nerves of your eyes
- Reduced white blood cell count , Severe anaemia
- Seizures, nervous disorders such as numbness, pain, furry sensation or tingling in the arms or legs
- Inflammation of the meninges (or brain lining) that is not caused by bacteria (aseptic meningitis)
- Acute liver failure in patients with Cockayne Syndrome (see section 2 “Warnings and precautions”)
- hearing impairment, hearing loss
- Ringing in the ears (tinnitus)
- Skin rash, blisters, fever or other signs and symptoms of hypersensitivity reactions
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Other side effects include

Common

- Yeasts and bacterial superinfections

Uncommon

- Darkened urine (due to a metabolite of metronidazole)

Rare

- Changes in ECG (electrical activity of the heart)

Very rare:

- Psychotic disorders, including states of confusion, hallucination,
- Headache, dizziness, drowsiness, fever, disturbance of sight and movement, giddiness, speech defects, convulsions
- Visual disturbances, e.g. double vision, short-sightedness
- Liver function disorders (such as elevated serum levels of certain enzymes and bilirubin)
- Allergic skin reactions like itching, hives
- Joint and muscle pain

Not known:

- Sickness, feeling sick, diarrhoea, inflammation of tongue or mouth, belching and bitter taste,
- metallic taste, pressure above the stomach, furry tongue
- Difficulty swallowing
- Reduced interest/appetite for food (anorexia)
- Sad (depressed) mood
- Sleepiness or sleeplessness, muscle twitching,
- Reddening and itching of the skin (erythema multiforme)
- Vein wall irritation (to the point of inflamed veins and thrombosis) after intravenous administration, states of weakness, fever

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 HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metronidazole 5mg/ml

Keep this medicine out of the sight and reach of children.

Keep bottles in the carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the container and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Use only if the solution is clear and free of visible particles, and the bottle and closure are intact.

This medicinal product is intended for single use only. Discard any unused portions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metronidazole 5mg/ml contains

- The active substance is metronidazole.
1 ml Metronidazole 5mg/ml solution for infusion contains 5 mg metronidazole.
One 100-ml polyethylene bottle contains 500 mg metronidazole.
- The other ingredients are sodium chloride, disodium phosphate dodecahydrate, citric acid, water for injections

What Metronidazole 5 mg/ml looks like and contents of the pack

Metronidazole 5 mg/ml is a clear, colourless or slightly yellowish aqueous solution.

Metronidazole 5 mg/ml is supplied in

- 100-ml polyethylene bottles,
available in packs of 10 × 100 ml, 20 × 100 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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The following information is intended for health-care professionals only:

This solution can be diluted prior to administration with sodium chloride 0.9 % w/v or glucose 5 % w/v solutions for infusion. For dilution procedures the usual precautions of asepsis must be followed.