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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What Metronidazole ABR is and what it is used for

Metronidazole ABR contains the medicine metronidazole. It is a synthetic antimicrobial agent of the group of nitroimidazoles, which enters the bacterial cell and destroys it.

Metronidazole ABR is used for the treatment of a variety of infections in adults and children, caused by metronidazole-susceptible bacteria and other micro-organisms. It is used in the cases, determined by the physician as requiring intravenous infusions of the product.

It is suitable for the treatment of:
- Infections of the genital system and abdominal organs (for example, abscesses in the abdomen and pelvis monor, peritonitis), central nervous system (brain abscess), heart, bones and joints, skin and soft tissues, respiratory system, tissues surrounding the teeth, infected wounds;
- Infection of the blood (including infections after delivery).

It is used for the prevention of infection after surgery, particularly of the large bowel and genitals.

2. What you need to know before you use Metronidazole ABR

Do not use Metronidazole ABR

- if you are allergic to metronidazole or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to other nitroimidazoles (a group of antibacterial agents);
- if you are in the first three months of pregnancy.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Metronidazole ABR.

Before starting treatment with this product, you should tell your doctor:

- if you have or have had in the past a liver disease

Your doctor will decide if in the course of treatment it is necessary to perform laboratory and other tests to monitor your liver function. In some cases, you may need to reduce your dose. In case of severe liver impairment, the blood levels of metronidazole may increase significantly and metronidazole may accumulate excessively in the body, due to its reduced decomposition in the liver. If signs of liver damage appear, the treatment should be discontinued.

- if you have or have had in the past a kidney disease

Metronidazole is excreted mainly by the kidneys from the body; therefore, in case of impaired kidney function, the medicine and the products from its decomposition may accumulate in the body.

- if you have a blood disease

In these cases, the product should be used very carefully. A regular monitoring of blood laboratory parameters (especially white blood cell counts) is required in a long-term treatment (more than 10 days).

- if you have a disease of the central or peripheral nervous system

If during the treatment with the product you get numbness and tingling in the extremities, dizziness, impaired balance and gait, seizures, you should tell your doctor immediately. This may be indicative of damage to the central or peripheral nervous system. Your doctor will decide whether to continue the treatment or to reduce the dose.
• if you suffer from porphyria
Porphyria is a hereditary liver disease, in which the body does not produce enough haemoglobin. The use of the product should be avoided in patients with porphyria.

• other
You should know that during the treatment with metronidazole and at least 48 hours after its termination, you must not consume alcohol, since severe physical discomfort may occur if you drink alcohol-containing drinks.

Other medicines and Metronidazole ABR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is important to know that this product may alter the effects of some concomitantly administered medicines. It is therefore particularly important to tell your doctor if you are taking medicines containing:

• warfarin or other anticoagulants (medicines for thinning the blood) as metronidazole enhances their effects. Your doctor will decide whether monitoring of certain laboratory parameters, such as prothrombin time, may be required;
• phenytoin (for the treatment of epilepsy) and barbiturates (sleeping pills), which reduce the effect of metronidazole and, in turn, it enhances their effects;
• lithium-containing medicines - metronidazole increases their harmful effect on the kidneys. Your doctor will decide whether you need to reduce the dose of lithium and whether monitoring of certain laboratory parameters, such as creatinine and electrolyte blood levels, may be required;
• cimetidine - slows down metronidazole decomposition in the liver;
• disulfiram (for the treatment of alcohol addiction) - acute psychoses are likely to occur, for which, metronidazole should be administered no sooner than 14 days after cessation of the treatment with disulfiram;
• 5-fluorouracil (for the treatment of tumour diseases) - metronidazole delays its excretion from the body, which may enhance its toxicity;
• cyclosporine (a medicine for reduction of the risk of transplant rejection) - there is a risk of an increase in its serum concentrations;
• busulfan (for the treatment of malignant blood diseases) - its blood concentrations may increase, which may lead to significant toxicity.

Metronidazole ABR with food, drink and alcohol
You must not consume alcohol during the treatment with metronidazole and at least 48 hours after its termination.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide whether you can be treated with metronidazole if you are pregnant or breast-feeding. Your doctor will evaluate the ratio between the benefits for you and the risks for your baby. The product should not be used in the first three months of pregnancy. You need to know that metronidazole is excreted in breast-milk.

**Driving and using machines**
It should be considered that metronidazole may cause dizziness, drowsiness, anxiety, temporary visual disturbances and convulsions, thus affecting the ability to drive and use machines. This is applies particularly to the side effects that result from the interactions of metronidazole and alcohol, when concomitantly used.

**Metronidazole ABR contains sodium chloride**
The product contains sodium chloride as an excipient, in an amount of approximately 13.5 mmol (310 mg) sodium per 100 ml infusion solution. This should be considered in patients on a sodium-restricted diet, for example, those with heart failure, high blood pressure, kidney diseases.

3. **How to use Metronidazole ABR**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Treatment of infections**

*Adults and children aged > 12 years*
The recommended daily dose is 1500 mg, given as three separate infusions into a vein, every 8 hours.

*Children aged > 8 weeks and < 12 years*
The recommended daily dose is 20-30 mg/kg, given as a single dose or three separate intravenous infusions every 8 hours. The daily dose can be increased to 40 mg/kg, depending on the severity of infection.
Children aged < 8 weeks
The recommended daily dose is 15 mg/kg, given as a single dose or two separate intravenous infusions every 12 hours.

Prevention of infections after surgery
Adults and children aged > 12 years
Immediately prior to surgery, a single dose of 500 mg is administered, which can be repeated every 8 hours.

Children aged < 12 years
A single dose of 20-30 mg/kg is administered 1-2 prior to surgery.

In newborns aged < 40 weeks, the product is administered as a single dose of 10 mg/kg prior to surgery.

Patients with liver problems
Your doctor will decide the dose of metronidazole that you need to receive. Typically, the daily dose should be reduced, depending on the severity of liver problems.

Patients with kidney problems
Metronidazole and its degradation products may be removed by haemodialysis for 8 hours; therefore, the medicine should be re-applied immediately after the procedure.

Method of administration
- You need to know that this product can be administered only by a medical professional in the form of an intravenous infusion, which means introduction of the medicine into a vein over a period of time.
- The product is administered as a continuous, slow intravenous infusion. After evaluation by the physician on the susceptibility to infection and the degree of improvement of your condition, the treatment should be continued as early as possible with metronidazole-containing products for oral use.
- The treatment usually lasts 7 days, but may be extended on the physician’s discretion.

If you use more Metronidazole ABR than you should
The dose required for your treatment is determined by your doctor, but if you think you have been administered a dose higher than the required, you should inform immediately your doctor.
The doctor will decide whether you need any kind of treatment, if you have been administered a higher dose.

**If you forget to use Metronidazole ABR**
A dose higher than the prescribed should not be used to make up for a forgotten dose. Talk to your doctor, who will decide the dose to continue your treatment.

**If you stop using Metronidazole ABR**
The treatment with this product should not be terminated arbitrarily, even if you feel better, because its possible therapeutic effect may not manifest fully. It is also necessary to know that in this way you enable the development of bacteria resistant to its action.

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

4. **Possible side effects**

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

The frequency of the reported side effects is, as follows:

**Common** - affects more than 1 in 100 and less than 1 in 10 users.

**Uncommon** - affects more than 1 in 1,000 and less than 1 in 100 users.

**Rare** – affects more than 1 in 10,000 and less than 1 in 1,000 users.

**Very rare** - affects less than 1 in 10,000 users.

**Not known** – cannot be estimated from the available data.

The following side effects may occur during the treatment with metronidazole:

**Blood and lymphatic system disorders**
Very rare: a reduction in the number to absence of the white blood cells, which increases the likelihood of infection, a reduction in the number of blood platelets (thrombocytes), which increases the risk of bleeding or bruising, a reduction in the number to absence of all blood cells.

Not known: a reduction in the number of one of the types of white blood cells.

**Immune system disorders**
Rare: severe allergic reactions;

Not known: a severe allergic reaction that causes swelling of the face and throat, hives (urticaria), fever.
Metabolism and nutrition disorders
Not known: severe to a complete lack of appetite.

Psychiatric disorders
Very rare: psychiatric disorders, including hallucinations and confusion;
Not known: depressed mood.

Nervous system disorders
Very rare:
- depression, fever, headache, hallucinations, paralysis, excessive sensitivity to light, impaired
coordination and movements, stiff neck, as well as balance, speech, gait disorders, uncontrolled eye
movements, tremor of the hands, which usually resolve after discontinuation of the treatment;
- dizziness, somnolence, convulsions, headache;
Not known: during the treatment with high doses and/or longer duration, impaired sensitivity and
seizures have been reported. In most cases, these symptoms have resolved upon discontinuation of the
treatment or reduction of the dose.

Eye disorders
Very rare: visual disturbances, such as double vision, myopia, transient in most cases.

Gastrointestinal disorders
Not known: taste disturbances, inflammation of mucous membranes in the mouth, red tongue, nausea,
vomiting, gastrointestinal disturbances, such as abdominal pain, diarrhoea.

Hepatobiliary disorders
Very rare: laboratory abnormalities related to liver function, hepatitis due to retention of bile, jaundice,
inflammation of the pancreas, which are reversible upon discontinuation of the treatment.

Skin and subcutaneous tissue disorders
Very rare: skin rash, hives with blistering, itching, flushing;
Not known: erythema multiforme (severe skin disease with blistering).

Musculoskeletal and connective tissue disorders
Very rare: pain in muscles and joints.

Renal and urinary disorders
Very rare: dark and red-brown coloured urine.
Administration site conditions
Common: pain or irritation at the administration site, inflammation of the vein.

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.

5. How to store Metronidazole ABR

Keep this medicine out of the sight and reach of children.
Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Shelf life after first opening: 3 hours.
To avoid contamination, the product should be used immediately after opening.
Store in the original package in order to protect from light.
In the case of freezing, thaw at a room temperature.

Do not use Metronidazole ABR if you notice changes in the appearance of the medicine.

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 ABR contains
- The active substance in one vial of 100 ml is metronidazole of 500 mg.
- The other ingredients (excipients) are citric acid monohydrate, disodium phosphate dodecahydrate, sodium chloride, water for injections.

What Metronidazole ABR looks like and contents of the pack
Metronidazole ABR solution for infusion is almost colorless to pale yellow liquid.
Colourless glass vials, closed with a rubber stopper and aluminum seal with a flip-off cap.
Pack size: 10 vials per carton.
Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd
Razgrad 7200, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd
Razgrad 7200, Bulgaria

This leaflet was last revised in November 2012.

The following information is intended for healthcare professionals only:

Information for healthcare professionals
The product should not be administered concurrently with other infusion solutions. The bank with a solution of metronidazole should not be added with other medicines outside the following:

- Cefuroxime is physically and chemically compatible with metronidazole;
- The following products are physically compatible, with regard to the pH and appearance, beyond the usual period of administration of metronidazole solution for infusion: amikacin sulphate, sodium ampicillin, carbenicillin sodium, cefazolin sodium, cefotaxime sodium, cephalothin sodium, chloramphenicol sodium succinate, clindamycin phosphate, gentamicin sulphate, hydrocortisone sodium succinate, disodium latamoxef, netilmicin sulphate and tobramycin sulphate;
- Metronidazole solution for infusion can be diluted in an appropriate volume of 0.9% sodium chloride, 5% dextrose or Ringer solution.