CEFOPERAZONE ABR 1 g powder for solution for injection
CEFOPERAZONE ABR 2 g powder for solution for injection
Cefoperazone

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
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2. What you need to know before you use Cefoperazone ABR
3. How to use Cefoperazone ABR
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6. Contents of the pack and other information

1. What Cefoperazone ABR is and what it is used for
Cefoperazone ABR contains the medicine cefoperazone, which is a synthetic antibiotic of the group of cephalosporins.
Cefoperazone ABR is used for the treatment of a variety of infections in adults and children, caused by cefoperazone-susceptible bacteria.
It is suitable for the treatment of:
- Infections of the respiratory tract, kidneys and urinary tract, abdominal organs, inflammation of the lining of the brain (meningitis), bones and joints, skin and soft tissues, genital system (for example, inflammation of the lining of the uterus), gonorrhoea and others.
- Infections of the blood (septicaemia).

It is used for the prevention of infections after surgery, particularly of the abdominal organs, genitals, heart, vessels, bones and joints.
Administered alone, this product can successfully treat most infections. It can also be used concomitantly with other antibiotics if the doctor deems it necessary.

2. **What you need to know before you use Cefoperazone ABR**

**Do not use Cefoperazone ABR:**
- if you are allergic to cefoperazone;
- if you are allergic to other cephalosporin antibiotics;
- if you are allergic to lidocaine (used to dissolve cefoperazone for intramuscular administration).

**Warnings and precautions**

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

Before starting treatment with this product, you should tell your doctor:
- if you have or have had in the past allergy to cephalosporin antibiotics, penicillins, lidocaine or other medicines

You need to know that in these cases the risk of severe allergic reactions is higher.

- if you have or have had a liver and/or a kidney disease

Your doctor will decide whether you require a change in the usual dose of administration of this medicine.

- if during the treatment with this medicine a gastrointestinal disorder appears, especially diarrhoea, or if you have previously experienced such events with antibiotic therapy

In the event of such a disorder, immediately consult a doctor. This may be a sign of acute intestinal inflammation (the so-called pseudomembranous colitis), which requires specific treatment. You need to know that in this case, treatment with the product should be discontinued and the medicines that inhibit intestinal motility (peristalsis) are contraindicated.

- if you are on a strict diet or have been recently on a diet of continuous feeding through intravenous infusions

In these cases, addition of vitamin K and monitoring of certain laboratory parameters, such as prothrombin time, may be required.

- if you have disturbances in the number of blood platelets (thrombocytes)
- if you are taking/using other medicines, especially aminoglycoside antibiotics.

You should know that during the treatment with cefoperazone and not less than 5 days after its termination, you must not consume alcohol, since severe physical discomfort may occur if you drink alcohol-containing drinks.

**Other medicines and Cefoperazone ABR**

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

Co-administration of Cefoperazone ABR and aminoglycoside antibiotics should be avoided, as kidney damage is likely to occur.
Cefoperazone ABR with food, drink and alcohol
You must not consume alcohol during the treatment with cefoperazone and not less than 5 days 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 cefoperazone if you are pregnant or breast-feeding. Your doctor will evaluate the ratio between the benefits for you and the risks for your baby.
You need to know that cefoperazone is excreted, although in small amounts, in breast milk.

Driving and using machines
Cefoperazone ABR is not expected to affect the ability to drive and use machines.

Cefoperazone ABR contains sodium
Each gram of Cefoperazone sodium contains approximately 34.5 mg (~1.5 mmol) sodium, which should be taken into consideration in patients on a sodium-restricted diet. These are patients with heart diseases, high blood pressure, kidney diseases.

3. How to use Cefoperazone 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.

Adults
The recommended daily dose is 2 – 4 g, divided in equal doses, administered every 12 hours.

Children
The recommended daily dose is 50 – 200 mg/kg, divided in equal doses, administered every 8 - 12 hours. The maximum daily dose should not exceed 12 g.

Patients with liver and/or kidney problems
Your doctor will decide the dose of cefoperazone that you need to receive. Typically, the daily dose should be reduced or increased, depending on the severity of the problems.

Method of administration
This product is applied as a short or continuous infusion into the vein or a deep intramuscular injection.
The content of the vial is pre-dissolved in the appropriate solvents.
If you use more Cefoperazone 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 Cefoperazone 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 Cefoperazone 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 cefoperazone:

Very common: increased number of the white blood cells (eosinophilia)
Common: a reversible reduction of the white blood cells (neutropenia), reduced numbers of certain white blood cells (neutrophiles), decreased haemoglobin and haematocrit, allergic reactions (including shock), diarrhoea, elevation of certain laboratory tests (SGOT, SGPT, alkaline phosphatase), rash, hives (urticaria).
Uncommon: vomiting.
Rare: reduction of certain blood components (hypoprothrombinaemia), inflammation of the vein in which the medicine was administered, fever.
Not known: pseudomembranous colitis (severe inflammation of the bowel, manifesting with severe, painful diarrhoea), decreased number of the blood platelets (thrombocytopenia), severe life-threatening allergic reactions, jaundice, severe disease accompanied by blistering of the skin, mouth,
eyes and genitals (Stevens-Johnson syndrome) or severe disease with blistering of the skin (toxic epidermal necrolysis), bleeding, pain at the injection site.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. **How to store Cefoperazone ABR**
Keep this medicine out of the sight and reach of children.
Store below 25°C.
Store in the original package in order to protect from light.
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.
Do not use this medicine 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 Cefoperazone ABR contains**
- The active substance in each vial is cefoperazone of 1 or 2 g.
- The product does not contain any other ingredients (excipients).

**What Cefoperazone ABR looks like and contents of the pack**
Cefoperazone ABR is a white or pale yellow powder.
Colourless glass vial, closed with a rubber stopper and sealed with an aluminium cap.
5 vials per carton.

**Marketing Authorisation Holder**
Antibiotic-Razgrad AD
Office 201, 68 “Aprilsko vastanie” Blvd
Razgrad 7200, Bulgaria

**Manufacturer**
Balkanpharma-Razgrad AD
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
The following information is intended for healthcare professionals only:

**Method of administration**

The product is administered by deep intramuscular injection, direct intravenous injection, in the form of short-term intravenous infusion over 15 to 60 minutes, or continuous intravenous infusion.

From a microbiological point of view, the ready-to-use solution should be used immediately. If not used immediately, storage times and conditions are the responsibility of the applier and should not be longer than 24 hours at 2-8°C.

**Preparation of solutions**

*Intravenous administration*

The content of the vial is dissolved in 5 ml per 1 g cefoperazone of any of the following solvents that are compatible and suitable for intravenous administration.

Compatible solutions for initial reconstitution: 5% glucose, 10% glucose, 5% glucose in 0.9% sodium chloride, 0.9% sodium chloride, 5% glucose in 0.2% sodium chloride solution, sterile water for injections.

For short-term intravenous infusion

Upon completion of the initial reconstitution, the total amount of the solution obtained is diluted further with 20 to 100 ml of some of the solutions for intravenous infusion, as follows: 5% glucose, 10% glucose, 5% glucose in Ringer's lactate, Ringer's lactate, 0.9% sodium chloride, 5% glucose in 0.9% sodium chloride, 5% glucose in 0.2% sodium chloride.

For continuous intravenous infusion

Upon completion of the initial reconstitution, the total amount of the solution obtained is diluted further to a final concentration of 2 mg – 25 mg/ml with some of the solutions for intravenous infusion, as follows: 5% glucose, 10% glucose, 5% glucose in Ringer's lactate, Ringer's lactate, 0.9% sodium chloride, 5% glucose in 0.9% sodium chloride, 5% glucose in 0.2% sodium chloride.

For direct intravenous injection

The maximum single dose of cefoperazone should not exceed 2 g in adults and 50 mg/kg in children. After reconstitution in a suitable solvent to a final concentration of 100 mg/ml cefoperazone, the solution is applied for not less than 3 minutes per 1 g of cefoperazone.
**Intramuscular administration**

Sterile water for injections can be used for the preparation of cefoperazone solution, intended for intramuscular administration.

In cases, where it is necessary to introduce solutions with concentration \( \geq 250 \text{ mg/ml} \), it is necessary to use a solution of lidocaine hydrochloride.

These solutions must be prepared by using sterile water for injections and 2% lidocaine hydrochloride, which is approximately 0.5% solution of lidocaine hydrochloride in the solution for administration.

It is advisable to perform the reconstitution in two stages:

**Step 1:** The required amount of sterile water for injections is added in the vial and the vial is shaken vigorously until complete dissolution of the contents;

**Step 2:** The required amount of 2% lidocaine hydrochloride is added to the solution obtained and the vial is shaken.

<table>
<thead>
<tr>
<th>Final concentration of cefoperazone</th>
<th>Step 1 Quantity of sterile water for injections</th>
<th>Step 2 Quantity of 2% lidocaine</th>
<th>Quantity that can be withdrawn from the vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 g cefoperazone</td>
<td>250 mg/ml 333 mg/ml</td>
<td>2.6 ml 1.8 ml</td>
<td>0.9 ml 0.6 ml</td>
</tr>
<tr>
<td>2 g cefoperazone</td>
<td>250 mg/ml 333 mg/ml</td>
<td>5.2 ml 3.9 ml</td>
<td>1.8 ml 1.2 ml</td>
</tr>
</tbody>
</table>

The solutions for administration are colourless, almost colourless to pale yellow in colour, depending on the concentration, which is not associated with the activity, efficacy and tolerability. Prior to administration, the solutions should be inspected visually for visible particles. Solutions should be used only if they are clear and free from visible particles.