Read all of this leaflet carefully before you start taking 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 Cefixime ABR is and what it is used for
2. What you need to know before you take Cefixime ABR
3. How to take Cefixime ABR
4. Possible side effects
5. How to store Cefixime ABR
6. Contents of the pack and other information

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

Cefixime ABR belongs to a group of medicines, called cephalosporins, which are used for the treatment of infections.

Cefixime ABR is indicated in adults and children for the treatment of:
- infection of the middle ear
- infection of the sinuses
- infection of the throat
- infection that causes sudden worsening of a persistent bronchitis
- pneumonia, acquired out of the hospital
- infections of the urinary tract.

2. What you need to know before you take Cefixime ABR

Do not take Cefixime ABR
- if you are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6). The allergic reaction may include rash, itching, difficulty in breathing or swelling of the face, throat or tongue;
- if you are allergic to other cephalosporin antibiotics;
- if you have ever had a severe allergic reaction to a penicillin antibiotic or any other beta-lactam antibiotic.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Cefixime ABR.

Before taking Cefixime ABR, you should tell your doctor:
- if you are allergic to penicillin antibiotics or any other antibiotic of the beta-lactam group. Not all people, allergic to penicillin, are allergic to cephalosporins. However, take special measures,
In patients developing severe allergic reactions or anaphylaxis (a severe allergic reaction, which causes difficulty in breathing or dizziness) after the administration of Cefixime ABR, the medicine should be stopped and adequate treatment should be instituted.

- if you have ever been told that your kidneys do not work properly; also, if you are undergoing some treatment (such as dialysis) for renal insufficiency. You may still receive Cefixime ABR, but you may need a lower dose.
- if you have severe or persistent diarrhoea, which may contain traces of blood and is combined with abdominal pain or spasms: these symptoms may present during or shortly after the treatment and give warning of a rare, but potentially life-threatening undesirable effect. Stop taking Cefixime ABR and contact your doctor immediately. Medicines that slow down or stop intestinal peristalsis should not be taken.

During the therapeutic course with Cefixime ABR, the likelihood of catching infections, caused by microbes irresponsible to the action of Cefixime ABR, may temporarily increase. Thrush (an infection caused by a fungus, called Candida) may occur.

Interference with laboratory tests
If you are going to have some blood or urine testing, tell your doctor that you receive Cefixime ABR, since cefixime may interfere with some of these test results.

Cefixime ABR may interfere with the results of some tests for detecting glucose in the urine (such as Benedict’s test or Fehling’s test). If you have diabetes and test your urine regularly, tell your doctor. This is needed because other tests for controlling your diabetes are to be used, whilst you are taking this medicine.

Cefixime ABR may interfere with the results of a blood test for antibodies, called the Coombs’ test.

Other medicines and Cefixime ABR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if:
- you have been on anticoagulant (for thinning the blood) treatment with medicines, such as warfarin.

Cefixime ABR with food, drink and alcohol
Cefixime ABR can be taken before or after meals. You should take the adequate amount of suspension with a glass of water.

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.

Driving and using machines
Usually, Cefixime ABR has no influence on the ability to drive or use machines. However, if you experience dizziness or vertigo, do not drive and do not operate machines.

Cefixime ABR contains sucrose
The product contains sucrose as ingredient (one dose of the prepared suspension contains about 2.5 g sucrose). If you have been told by your doctor that you have intolerance to some sugars, ask your doctor for advice before you start taking this product.
3. How to take Cefixime ABR

Always take 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 dose is 200–400 mg daily, which means an intake of 10 – 20 ml of Cefixime ABR suspension. The prescribed dose can be received in one intake as a single dose or as two individual doses. If your doctor has prescribed to you one dose daily, it should be taken every 24 hours. If your doctor has prescribed to you two doses daily, each dose should be taken every 12 hours (it may turn more convenient to take the one dose in the morning and the other in the evening). This medicine should be taken at the same time each day.

Elderly (over 64 years of age)
In the elderly, the dosage is the same as in adults with normal renal function.

Patients with kidney problems
In elderly patients with kidney problems, the dose of Cefixime ABR may need to be reduced. Your doctor will calculate your correct dose, depending on the blood or urine test results, which are indicative of how properly your kidneys are functioning, as well as on the severity of your infection.

Data on the use of Cefixime ABR in children and adolescents with kidney problems are insufficient. Therefore, Cefixime ABR is not recommended for use in these patients.

Use in children and adolescents
Children over 10 years of age
In children over 10 years of age, a dosage the same as that in adults may be administered.

Children over 6 months to 10 years of age
Your doctor will determine the exact dosage, but for your information, the recommended doses according to the age are listed below:
- 6 months - 1 year: 3.75 ml daily
- 1 - 4 years: 5 ml daily
- 5 - 10 years: 10 ml daily

Children with body weight more than 50 kg or over 10 years of age should be treated at the daily doses recommended for the adults.

Children under 6 months of age
Cefixime ABR is not recommended for use in children under 6 months of age.

If you take more Cefixime ABR than you should
If you have accidentally taken a greater amount of the suspension or a child has swallowed a certain amount of Cefixime ABR suspension, contact the emergency centre at the nearest hospital or your doctor immediately.

If you forget to take Cefixime ABR
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. However, if the intake of your next dose is in less than 6 hours, skip the forgotten dose and follow your regular dosing schedule.

If you stop taking Cefixime ABR
Do not stop the treatment earlier, because it is important to complete the full course of treatment with this medicine, in order to reduce the likelihood of an infection re-occurrence.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects are serious and requiring immediate action, if you experience them. You should stop taking cefixime and go to the doctor immediately upon occurrence of the following symptoms:

**Rare side effects (affect less than 1 in 1,000 patients) include:**
- severe allergic reaction, which causes swelling of the face or throat, which may result in severe difficulty in breathing

**Very rare side effects (affect less than 1 in 10,000 patients) include:**
- watery and severe diarrhoea, which may contain traces of blood
- a sudden allergic reaction with difficulty in breathing, rash, wheezing and a drop of the arterial pressure
- severe, extensive rash with blistering

The following side effects have also been reported:

**Common side effects (affect less than 1 in 10 patients) include:**
- diarrhoea

**Uncommon side effects (affect less than 1 in 100 patients) include:**
- headache
- nausea (feeling sick)
- vomiting (being sick)
- stomach (abdominal) pain
- changes in the laboratory test results indicative for the functioning of the liver
- skin rash

**Rare side effects (affect less than 1 in 1,000 patients) include:**
- infections, caused by microbes irresponsive to the action of cefixime, e.g. thrush
- loss of appetite
- flatulence (wind)
- changes in the laboratory test results indicative for the functioning of the kidneys
- fever
- allergic reaction
- dizziness
- itching of the skin
- inflammation of the mucosa lining the mouth and/or other internal surfaces

**Very rare side effects (affect less than 1 in 10,000 patients) include:**
- reduction of the various blood cell counts (the symptoms may include fatigue, newly occurred infections and bruising or bleeding after a minor trauma)
- agitation and overactivity
- liver problems, including jaundice (yellowing of the skin or white of the eyes)
- inflammation of the kidneys, which may cause swelling of the ankles or high blood pressure
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 Cefixime ABR

Keep this medicine out of the sight and reach of children.
Do not use Cefixime ABR after the expiry date (EXP:) which is stated on the pack. The expiry date refers to the last day of that month.

Store below 25°C.

The prepared suspension can be used for 14 days and should also be stored at a temperature below 25°C.

Store the bottle in the cardboard carton.

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 Cefixime ABR contains
- The active substance is cefixime. 5 ml suspension contains 100 mg cefixime, as trihydrate.
- The other ingredients are xanthan gum; sodium benzoate; silica, colloidal anhydrous; strawberry flavour; sucrose.

Strawberry flavour contains naturally identical flavours; maltodextrin; triethyl citrate (E 1505); propylene glycol (E 1520).

What Cefixime ABR looks like and contents of the pack

Appearance: white to pale yellow powder with characteristic flavour.
Appearance of the prepared suspension: cream to pale yellow colour and characteristic flavour.

The product is supplied in amounts for obtaining oral suspension of 50 ml and 100 ml.
The pack consists of amber glass bottles, closed with plastic caps fitted with a temper evident ring.
The bottles are inserted in cartons, with a dosing pipette and a patient leaflet.

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

Manufacturer
Balkanpharma-Razgrad AD
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD
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