

Package leaflet: Information for the patient

Lincomycin ABR 500 mg hard capsules

lincomycin

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Lincomycin ABR is a broad-spectrum antibiotic that stops the development of pathogens and destroys them at high doses.

Lincomycin ABR is used to treat infections caused by lincomycin-sensitive microorganisms such as:

- Ear, nose and throat (ENT) infections and respiratory tract infections - bronchitis, pneumonia, lung abscesses;
- Infections of the gastrointestinal tract - peritonitis, inflammation in the abdominal cavity;
- Biliary tract infections;
- Gynecological infections - vaginitis, endometritis, inflammation of the lower pelvic organs, postoperative vaginal infections;
- Bone and joint infections;
- Skin and soft tissue infections, furuncle and secondary wound infections;
- Sepsis;
- As a concomitant treatment in surgery;
- Preoperative prevention.

Lincomycin ABR is suitable as an alternative treatment for patients allergic to penicillin.

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

Do not take Lincomycin ABR if:

- you are allergic to lincomycin or clindamycin or any of the other ingredients of this medicine (listed in section 6);
- you have meningitis (inflammation of the meninges);
- if you are pregnant or breastfeeding

Warnings and precautions

Talk to your doctor before taking Lincomycin ABR.

Lincomycin ABR should only be used to treat severe infections when another antibacterial agent is contraindicated. The product should not be used for non-bacterial infections, e.g. of the upper respiratory tract.

Lincomycin ABR should be used with caution in patients with gastrointestinal disorders (especially colitis), as it can cause pseudomembranous colitis (a complication that results from an imbalance of bacteria normally found in the intestine, which causes inflammation of the intestinal mucosa with severe diarrhea and severe abdominal cramps). Usually, mild forms disappear after stopping treatment. Moderate to severe cases require treatment with vancomycin, corticosteroids, proteins and a lot of fluids.

Allergic reactions (skin rashes, urticaria, redness) may occur. In such patients, treatment should be discontinued and appropriate therapy instituted.

In cases of hypersensitivity to clindamycin, cross-allergy may occur. Particular caution is required when administering the antibiotic in patients who have had allergic manifestations.

Prolonged treatment with lincomycin may lead to overgrowth of non-susceptible microorganisms, such as yeast and additional infection. The product should be discontinued and appropriate treatment instituted.

Kidney, liver and haematopoietic function should be monitored with long-term treatment.

Other medicines and Lincomycin ABR

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

Lincomycin inhibits neuromuscular transmission, and when administered together with some medicines (muscle relaxants or general anesthetics) used in surgery and anesthesiology, a cumulative effect may be observed, which can lead to muscle weakness and even respiratory arrest.

The product should not co-administered with the antibiotics erythromycin or chlornithromycin due to the existing antagonism (opposite effect) between them.

Co-administration of lincomycin with medicines, which slow down the intestinal peristalsis may increase their effect and worsen the patient's condition in case of colitis.

Lincomycin ABR with food and drink

There is no evidence of the need for a special diet or restrictions on certain food and drinks during treatment with this product.

To avoid the irritating effects of Lincomycin ABR on the stomach mucosa, the antibiotic should be taken with plenty of fluids.

Pregnancy and breast-feeding

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.

Lincomycin ABR crosses the placenta and reaches the fetal bloodstream. The safety of the antibiotic during pregnancy has not been established. Therefore, the use of Lincomycin ABR during pregnancy is contraindicated.

The product is excreted in breast milk, so it is recommended to discontinue breast-feeding while taking Lincomycin ABR.

Driving and using machines

Lincomycin ABR has no influence on the ability to drive and use machines.

3. How to use Lincomycin ABR

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

Lincomycin ABR is given by the mouth at the following doses:

Adults: 500 mg 3 times daily for 8 hours; in severe infections - 500 mg 4 times daily for 6 hours

Children: 30 mg/kg for 24 hours, divided into 3 or 4 doses; for serious infections 60 mg/kg for 24 hours divided into 3 or 4 doses.

The duration of treatment varies widely depending on the severity of the disease. For infections caused by beta-hemolytic streptococci and for the prevention of rheumatic attacks, treatment for at least 10 days is required.

Lincomycin ABR is taken 1 hour before or 2 hours after a meal with a lot of liquids.

If you take more Lincomycin ABR than you should

If you take a higher dose than you should, talk to your doctor immediately.

Nausea, vomiting, abdominal pain, skin rashes, and rarely anaphylaxis (severe allergic reaction) usually occur with overdose. In the event of a critical or life-threatening reaction, the patient should be treated immediately with adrenaline, intravenous corticosteroids, antihistamines, oxygen supplementation, and, if required artificial ventilation.

Lincomycin cannot be effectively excreted by hemo- or peritoneal dialysis.

If you forget to take Lincomycin ABR

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual.

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

If you are not sure what the side effects listed below are, ask your doctor to explain them to you.

Gastrointestinal disorders: nausea, vomiting, abdominal pain, diarrhea. Treatment with lincomycin can cause pseudomembranous colitis (a severe complication characterized by prolonged and persistent diarrhea, painful intestinal spasms, and bleeding of the mucous membrane).

Immune system disorders: skin rashes, urticaria, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome). Severe allergic reactions (angioedema, serum sickness, anaphylaxis) are rare.

Blood and lymphatic system disorders: With prolonged treatment, abnormalities in the number of individual blood cells (neutropenia, leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia, and pancytopenia) may occur.

Hepatobiliary disorders: Impaired liver function or jaundice may occur with prolonged treatment.

Renal and urinary disorders: impaired kidney function, resulting in an increased blood creatinine and urea, decreased urine production, protein in the urine.

Nervous system disorders: Sensory disturbances, dizziness and tinnitus, sometimes suppression of neuromuscular transmission, may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel. +359 28903417
Website: www.bda.bg

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

5. How to store Lincomycin ABR

Store below 25°C.

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

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 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 Lincomycin ABR contains

- The active substance is lincomycin hydrochloride. Each capsule contains 500 mg of lincomycin as lincomycin hydrochloride.
- The other ingredients are: *capsule content:* Magnesium stearate. *Hard gelatine capsule shell:* titanium dioxide E 171, indigo carmine E 132, gelatine

What Lincomycin ABR looks like and contents of the pack

Appearance: Hard, cylindrical blue gelatine capsules.

Pack: 10 Lincomycin ABR 500 mg capsules in a PVC/Aluminium foil blister, 2 blisters per pack.

Marketing Authorisation Holder

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Manufacturer

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