

Package leaflet: Information for the patient

Clindamycin ABR 150 mg capsules, hard

Clindamycin ABR 300 mg capsules, hard

Clindamycin ABR 600 mg capsules, hard

Clindamycin

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.

What is in this leaflet

1. What Clindamycin ABR is and what it is used for
2. What you need to know before you take Clindamycin ABR
3. How to take Clindamycin ABR
4. Possible side effects
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1. What Clindamycin ABR is and what it is used for

Clindamycin ABR contains clindamycin – an antibiotic of the group of lincosamides. It is active against a large number of pathogens causing some common infections in humans.

It is used for both adults and children in the treatment of infections caused by bacteria sensitive to clindamycin and other microorganisms, such as:

- respiratory tract infections (inflammation of the tonsils, throat, ear, bronchi, pneumonia)
- infections of skin and soft tissues (acne, infected wounds, abscesses, inflammation of the hair follicles)
- infections of bones and joints
- infections of the genital and abdominal organs, including inflammation of the cervix caused by a microorganism called Chlamydia
- infections of the teeth and dental tissues
- certain specific infections in patients with AIDS
- scarlet fever (a type of measles, characterised by fever, typical rash and inflammation of tonsils)

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

Do not take Clindamycin ABR

- if you are allergic to clindamycin or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to other antibiotics of the group of lincosamides.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin ABR.

You need to tell your doctor:

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

Your doctor will decide whether it is necessary to monitor the health of your liver and kidneys during the treatment with this medicine.

- if you have experienced diarrhoea whilst taking antibiotics

If diarrhoea appears or you have loose stools during or after the treatment with this medicine, contact your doctor and do not take other medicines before consulting him/her. Tell your doctor if your diarrhoea continues.

Upon occurrence or suspected occurrence of allergic reactions you should **immediately** stop taking the medicine and contact your doctor.

Other medicines and Clindamycin 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 simultaneously administered medicines. It is, therefore, particularly important to tell your doctor if you are taking:

- the antibiotic erythromycin - your medicine may lower its activity.
- tubocurarine, alcuronium and other neuromuscular blockers-clindamycin may potentiate their effects.
- warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.

Clindamycin ABR with food, drink and alcohol

Clindamycin ABR can be taken regardless of meals. The capsules should be taken with plenty 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.

Clindamycin crosses the placenta and is excreted in breast milk. During pregnancy and breast-feeding, it should be used only in cases of demonstrated need.

Your doctor will decide whether you may be treated with clindamycin if you are pregnant. He/she will evaluate the ratio of the benefit for you and the risks for your baby.

Your doctor will decide whether you should discontinue breast-feeding during the treatment with clindamycin.

Driving and using machines

There are no data of untoward influence of Clindamycin ABR on the ability to drive and use machines.

Clindamycin ABR contains lactose monohydrate

This product contains as an excipient lactose (milk sugar), making it unsuitable for people with congenital or acquired intolerance to some sugars. If you have been told by your doctor that you have such an intolerance, contact your doctor before taking this product.

3. How to take Clindamycin 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.

Your doctor will determine the appropriate dose and regimen for the treatment of your disease. In some cases, your doctor may administer clindamycin therapy at doses other than those mentioned below.

The recommended dose is:

Adults and children over 14 years

Daily dose of 600 – 1,800 mg, -divided in 2, 3 or 4 equal doses.

Children under 14 years

Daily dose of 8 – 25 mg/kg, divided in 3 or 4 equal doses.

For children weighing 10 kg or less, the recommended dose is 37.5 mg three times daily given as age-appropriate formulation.

Clindamycin ABR capsules are not suitable for use in young children due to the impossibility of accurate dosing.

The duration of treatment varies widely depending on the severity of the disease. In infections caused by beta-hemolytic streptococci and for the prevention of rheumatic recurrence duration of treatment should be at least 10 days.

Elderly

No dose adjustment is required in patients with preserved hepatic and renal function.

Renal and hepatic impairment

Usually, no dose adjustment is required; however, your doctor may decide treating at doses other than the recommended or taking the capsules over longer intervals.

Method of administration

Clindamycin ABR capsules are swallowed whole with plenty of water to avoid oesophageal irritation.

If you take more Clindamycin ABR than you should

If you take more than the prescribed dose, promptly contact your doctor or go to the nearest hospital.

Bring a pack of the medicine, whether there is a certain amount or not.

The doctor will decide if treatment is needed if you have taken a higher dose.

If you forget to take Clindamycin ABR

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Clindamycin ABR

Do not stop taking this medicine if you feel better, unless you have been told by your doctor. If you stop taking the medicine too soon, the infection may return or your condition may worsen.

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.

Contact **immediately** your doctor if you experience:

- sudden wheezing, difficulty breathing, swelling of the eyelids, face or lips, rash and itching (especially of the entire body);
- severe or persistent diarrhoea that contains blood or mucus during the treatment or after its discontinuation. This may be a manifestation of a serious inflammatory bowel disease;
- severe skin rash accompanied by redness and scaling and blistering.

During the treatment with clindamycin the following side effects may occur:

Common side effects (may affect up to 1 in 10 people): abdominal pain, diarrhea, pseudomembranous colitis, abnormal liver function tests

Uncommon side effects (may affect up to 1 in 100 people): nausea, vomiting, maculopapular rash (rash with eruptions of different size), urticaria (hives).

Not known (frequency cannot be estimated from the available data): infections of the vagina; agranulocytosis (severe reduction in the number of certain white blood cells, which increases the likelihood of infection), reduced number of leukocytes and neutrophils in the blood (certain type of white blood cells, which increases the risk of infection), thrombocytopenia (decrease in the number of platelets, which increases risk of bleeding or bruising), increased numbers of eosinophils (certain type of cell) in the blood; severe allergic reaction that causes difficulty breathing or dizziness; drug reaction manifested by rash, fever, eosinophilia and systemic disorder (DRESS syndrome; abnormal taste; ulceration of the gullet, inflammation of the lining of the esophagus, jaundice, severe skin diseases accompanied by blistering of the skin, mouth, eyes and genitals, acute generalized exanthematous pustulosis (AGEP), erythema multiforme, exfoliative dermatitis, bullous dermatitis, morbilliform rash, itching

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"Damyán Gruev"street
1303 Sofia
Tel .: +35 928903417
website: www.bda.bg

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

5. How to store Clindamycin ABR

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

Do not use Clindamycin ABR after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Clindamycin ABR if you notice changes in the appearance of the capsules.

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 Clindamycin ABR contains

Clindamycin ABR 150 mg capsules, hard

- The active substance per capsule is clindamycin of 150 mg.
 - The other ingredients are silica, colloidal anhydrous; lactose monohydrate/maize starch; magnesium stearate.
- The hard gelatin capsule contains titanium dioxide (E171), indigo carmine (E132) and gelatin.

Clindamycin ABR 300 mg capsules, hard

- The active substance per capsule is clindamycin of 300 mg.
 - The other ingredients are silica, colloidal anhydrous; lactose monohydrate/maize starch; magnesium stearate.
- The hard gelatin capsule contains titanium dioxide (E171), indigo carmine (E132) and gelatin.

Clindamycin ABR 600 mg capsules, hard

- The active substance per capsule is clindamycin of 600 mg.
 - The other ingredients are silica, colloidal anhydrous; lactose monohydrate/maize starch; magnesium stearate.
- The hard gelatin capsule contains titanium dioxide (E171) and gelatin.

What Clindamycin ABR looks like and contents of the pack

Clindamycin ABR 150 mg capsules, hard

Hard gelatin capsules with blue body and blue cap.
8 (eight) hard gelatin capsules per PVC/AL foil blister.
2 (two) blisters with a leaflet/information for the patient per carton.

Clindamycin ABR 300 mg capsules, hard

Hard gelatin capsules with white body and blue cap.
8 (eight) hard gelatin capsules per PVC/AL foil blister.
2 (two) blisters with a leaflet/information for the patient per carton.

Clindamycin ABR 600 mg capsules, hard

Hard gelatin capsules with white body and white cap.
6 (six) hard gelatin capsules per PVC/AL foil blister.
2 (two) or 5 (five) blisters with a leaflet/information for the patient per carton.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
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7200, Razgrad, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD
68 “Aprilsko vastanie” Blvd.
7200, Razgrad, Bulgaria

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

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