

Package leaflet: Information for the patient

Clindamycin EQL Pharma 150 mg capsules, hard Clindamycin EQL Pharma 300 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. See section 4.

What is in this leaflet

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

1. What Clindamycin EQL Pharma is and what it is used for

Clindamycin EQL Pharma is a bactericidal agent (antibiotic). Clindamycin EQL Pharma is used for the treatment of infections in the pharynx and in skin and soft tissues.

2. What you need to know before you take Clindamycin EQL Pharma

Do not take Clindamycin EQL Pharma

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to lincomycin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin EQL Pharma:

- if you have, or have previously had, a bowel disease. If you have, tell your doctor about this before you start treatment with Clindamycin EQL Pharma.
- if you have impaired liver or kidney function

In case of long-term treatment, liver and kidney function and blood should be examined regularly by the physician.

Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

Other medicines and Clindamycin EQL Pharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also applies to non-prescription drugs, including (traditional) herbal medicines and herbal remedies. Some medicines may affect the effects of this medicine, or this medicine may affect the effects of other medicines used at the same time.

It is especially important for your doctor to know if you are taking:

- muscle relaxant drug products
- erythromycin, clarithromycin, telithromycin, rifampicin (antibiotics, used to treat infections)
- itraconazole, voriconazole (used to treat fungal infections)
- ritonavir, cobicistat (used against HIV)
- St. John's wort (*Hypericum perforatum*) (used against mild depression and mild anxiety)
- carbamazepine, phenytoin and phenobarbital (used against epilepsy)
- dihydroergotamine, ergotamine (used against migraine)
- ergometrin (used in childbirth to reduce blood loss)
- midazolam, triazolam (sedatives, hypnotics)
- amiodarone, quinidine (used to treat irregular heart rhythm)
- cisapride (used in gastrointestinal disorders)
- pimozide (used in mental health problems)
- Alfuzosin (used to treat benign prostatic hyperstimulation)
- simvastatin, lovastatin (cholesterol lowering agents)
- Sildenafil (used for erection problems and for high blood pressure in the lungs)
- Warfarin or similar medicines (used to make the blood thinner) as this may increase risk for bleeding. The doctor may need to conduct regular tests of your blood to see how well your blood coagulates

Infections

The use of clindamycin may cause overgrowth of organisms that are not sensitive to clindamycin, especially yeast. Contact your doctor as soon as you suspect you have developed such an infection.

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.

Pregnancy

There is a risk that the fetus will be affected. Therefore, consult a doctor before using Clindamycin EQL Pharma. Clindamycin EQL Pharma should not be used during the first three months of pregnancy because there is insufficient information on safety.

If you are pregnant, you should only use Clindamycin EQL Pharma after in-depth discussion with your doctor who will determine if this treatment is appropriate for you.

Breast-feeding

There is a risk that breastfeeding children will be affected. Therefore, do not use Clindamycin EQL Pharma during lactation.

Driving and using machines

This medicine has no effect on the ability to drive and use machines.

Clindamycin EQL Pharma contains lactose monohydrate

Clindamycin EQL Pharma capsules contain *lactose*. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Clindamycin EQL Pharma

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

The dose is determined by a doctor that adjust it individually to you. The capsules should be swallowed whole with a glass of water and taken in a sitting or standing position. Clindamycin EQL Pharma can be taken with or without food.

It is important that the entire cure is completed as instructed, otherwise the infection may flare up again.

Use for children and adolescents

If the child can't swallow capsules, it is recommended to use granules for oral solution instead.

If you take more Clindamycin EQL Pharma than you should

If you have taken too many tablets, or if a child has taken medicine by accident, contact a doctor or the Hospital Emergency Department for the assessment of the risk and advice.

If you forget to take Clindamycin EQL Pharma

Do not take a double dose to make up for a forgotten dose. If you have any further questions on 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.

Contact immediately your doctor or nurse if you experience:

- severe, persistent or bloody diarrhea (which may be accompanied by stomach pains or fever) This may be a manifestation of severe bowel inflammation or inflammation of the colon mucosa (pseudomembranous colitis). This common side effect can, in very rare cases, develop into life-threatening complications.
- sudden wheezing, difficulty breathing or swallow, swelling of the eyelids, face or lips, rash and itching (especially if itching occurs over the entire body) This may be a manifestation of a severe hypersensitivity reaction (occurring in an unknown number of users).
- a drug reaction with symptoms such as fever, skin rash, altered blood image, enlarged lymph nodes and internal organs (DRESS syndrome, occurring in an unknown number of users)
- an extremely severe allergic reaction with skin rash usually in the form of blisters or sores in the mouth and eyes as well as other mucous membranes such as genitalia (occurring in an unknown number of users).
- inflamed and scaly skin, severe widespread skin damage (skin dermatitis of the epidermis and superficial mucous membranes) (occurring in an unknown number of users)
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

Clindamycin EQL Pharma may in rare cases affect the white blood cells so that the infection defence deteriorates. If you get an infection with symptoms such as fever with severe deterioration of the general condition or fever with local infectious symptoms such as sore throat or difficult urination, seek medical advice immediately, so that you can exclude a white blood cell deficiency (so called agranulocytosis, occurring in an unknown number of users). It is important that you then inform about your medication.

Other side effects:

Common side effects (may affect up to 1 in 10 people):

- abdominal pain
- diarrhea
- abnormal liver function tests

Uncommon side effects (may affect up to 1 in 100 people):

- hives (rashes)
- nausea
- vomiting

Not known (frequency cannot be estimated from the available data):

- diarrhea caused by the bacterium *Clostridium difficile*
- infections of the vagina
- decreased amount of one or more types of white blood cells (neutropenia, leukopenia)
- decreased amount of platelets
- increased amount of certain white blood cells (eosinophilia)
- changed taste
- ulcers in the esophagus
- inflammation of the esophagus
- jaundice
- allergic reactions
- measles-like rashes
- itching

Fungal overgrowth can cause infection in the mouth and genitals.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects **directly via the national reporting system listed in Appendix V.*** By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin EQL Pharma

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

This medicinal product does not require any special storage conditions.

Do not use Clindamycin EQL Pharma after the expiry date which is stated on the carton after “EXP”. 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 Clindamycin EQL Pharma contains

- The active substance is clindamycin 150 mg or 300 mg respectively.
- The other ingredients are silica, colloidal anhydrous; lactose monohydrate, maize starch; magnesium stearate, titanium dioxide (E171), indigo carmine (E132) and gelatin.

What Clindamycin EQL Pharma looks like and contents of the pack

150 mg capsules, hard

Hard gelatin capsules, 17.5 mm, with blue body and blue cap.

PVC/AL foil blister: 32 and 40 hard capsules

Bottle HDPE with cap of polypropylene: 45, 100 and 105 hard capsules

300 mg capsules, hard

Hard gelatin capsules, 21.7 mm, with white body and blue cap.

PVC/AL foil blister: 21 and 32 hard capsules.

Bottle HDPE with cap of polypropylene: 100 and 105 hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in

2021-12-01