

Package leaflet: Information for the patient

Clindamycin Actavis 150 mg hard capsules

Clindamycin Actavis 300 mg hard capsules

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

Clindamycin Actavis is an antibacterial agent (antibiotic) used to treat infections of the throat, skin and soft tissues.

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

Do not take Clindamycin Actavis

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin Actavis

- if you have or have previously had, any bowel disease. If you have, you should tell your doctor before starting treatment with Clindamycin Actavis.
- if you have impaired liver or kidney function.

If you have to take Clindamycin Actavis for a long time, your doctor may arrange regular liver, kidney and blood tests.

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.

If you develop severe or prolonged or bloody diarrhoea during or after using Clindamycin Actavis **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

Other medicines and Clindamycin Actavis

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 can affect the way this medicine works, or the medicine itself can reduce the effectiveness of other medicines taken at the same time. These include:

- muscle relaxants
- erythromycin, clarithromycin, telithromycin, rifampicin (antibiotics used to treat infections).
- itraconazole, voriconazole (used for fungal infections)
- ritonavir, cobicistat (used for HIV)
- St. John's wort (*Hypericum perforatum*) (used for mild depression and mild anxiety)
- carbamazepine, phenytoin and phenobarbital (used for epilepsy)
- dihydroergotamine, ergotamine (used for migraine)
- ergometrine (used in childbirth to reduce blood loss)
- midazolam, triazolam (sedatives, sleeping aids)
- amiodarone, quinidine (used to treat irregular heart rhythm)
- cisapride (used for gastrointestinal disorders)
- pimozide (used for psychological problems)
- alfuzosin (used for benign prostatic hyperplasia)
- simvastatin, lovastatin (cholesterol-lowering drugs)
- sildenafil (used for erectile dysfunction and high blood pressure in the lungs)
- 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.

Infections

Use of clindamycin can cause overgrowth of organisms that are not sensitive to clindamycin, especially yeast fungus. Contact your doctor as soon as possible if you suspect that you have developed such an infection.

Clindamycin Actavis with food and drink

The capsules can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There is a risk that the foetus may be affected. Therefore, consult a doctor before using Clindamycin Actavis. Clindamycin Actavis should not be used during the first three months of pregnancy because there is not enough information about its safety.

If you are pregnant, you should only use Clindamycin Actavis after detailed discussion with your doctor who will decide if this treatment is suitable for you.

Breast-feeding

There is a risk that breastfed babies may be affected. Talk to your doctor before using Clindamycin Actavis when you are breastfeeding.

Driving and using machines

This medicine has no effects on the ability to drive or use machines.

Clindamycin Actavis contains 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.

Clindamycin Actavis contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. How to take Clindamycin Actavis

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 your doctor who will adjust it to your individual needs. The capsules should always be swallowed whole with at least half a glass of water and taken in a sitting or standing position. Clindamycin Actavis can be taken with or without food.

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

Use in children and adolescents

If your child is unable to swallow capsules, it is recommended that an alternative formulation of clindamycin, e.g. granules for oral solution, is used. The prescribing doctor will adjust the dose according to the child's body weight.

If you take more Clindamycin Actavis than you should

If you have accidentally taken too many Clindamycin Actavis capsules or if, for example a child has ingested the medicine by mistake, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Clindamycin Actavis capsules left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take Clindamycin Actavis

If the forgotten dose is just a few hours late, take it straight away. If it is nearly time for your next dose then miss out the forgotten one. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Clindamycin Actavis

If you stop taking the medicine too soon your infection may come back again or get worse. Do not stop taking Clindamycin Actavis unless your doctor tells you to.

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.

Tell your doctor immediately if you develop:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This may be a sign of severe intestinal inflammation or inflammation of the mucous membrane of the large intestine (pseudomembranous colitis). This common side effect can in very rare cases develop into life-threatening complications.
- sudden wheezing, difficulty in breathing or swallowing, swollen eyelids, face or lips, rash or itching (especially affecting the whole body). This may be a sign of a serious hypersensitivity reaction (occurs in an unknown number of users).
- a drug reaction with symptoms such as fever, skin rash, changes in blood counts, enlarged lymph nodes and effects on internal organs (DRESS syndrome, occurs in an unknown number of users).
- an extremely severe allergic reaction with a skin rash usually in the form of blisters or sores in the mouth and eyes and other mucous membranes such as the genitals (occurs in an unknown number of users).
- inflamed and scaly skin, severe widespread skin damage (skin detachment of the epidermis and superficial mucous membranes) (occurs in an unknown number of users).

- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea (occurs in an unknown number of users).

In rare cases, Clindamycin Actavis may affect white blood cells, making your defence against infection weaker. If you develop an infection with symptoms such as fever with a severe worsening of your general condition or fever with local symptoms of infection such as sore throat/throat/mouth or difficulty urinating, you should immediately seek medical attention to rule out a white blood cell deficiency (agranulocytosis, occurs in an unknown number of users) by blood test. It is important that you inform your doctor about your medication.

Other side effects

Common (may affect up to 1 in 10 people)

- abdominal pain
- diarrhoea
- abnormal liver values

Uncommon (may affect up to 1 in 100 people)

- hives or other skin rashes
- vomiting
- nausea

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

- diarrhoea caused by the bacterium *Clostridium difficile*
- infection of the vagina
- decreased amount of one or more types of white blood cells (neutropenia, leukopenia)
- reduced platelet count (thrombocytopenia)
- increased amount of certain white blood cells (eosinophilia)
- change in taste
- ulcers in the esophagus
- inflammation of the oesophagus
- jaundice
- allergic reactions
- measles-like rash
- itching

Fungal overgrowth can cause infection of the oral cavity and genitals.

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 [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 Actavis

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister 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 Actavis contains

- The active substance is clindamycin.
- The other ingredients are:
 - Capsule contents: lactose, corn starch, talc, magnesium stearate
 - Capsule shell: titanium dioxide (E171), gelatin, water, sodium lauril sulfate
 - Printing ink: shellac, propylene glycol, black iron oxide (E172), potassium hydroxide

What Clindamycin Actavis looks like and contents of the pack

Clindamycin Actavis 150 mg are white hard capsules marked with 'A714' on the cap in black ink.
Clindamycin Actavis 300 mg are white hard capsules marked with 'A718' on the cap in black ink.

Pack sizes

Blisters: 12, 15, 16, 20, 24, 30, 32, 40, 100 and 104 hard capsules
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 03/2023.

[To be completed nationally]