

Package leaflet: Information for the user

Clindamycin Orifarm 150 mg capsules, hard

clindamycin

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

1. What <{(Invented) name}> is and what it is used for
2. What you need to know before you take <{(Invented) name}>
3. How to use <{(Invented) name}>
4. Possible side effects
5. How to store <{(Invented) name}>
6. Contents of the pack and other information

1. What <{(Invented) name}> is and what it is used for

<{(Invented) name}> 150 mg capsules, hard (called <{(Invented) name}> in the rest of this leaflet) belong to a group of medicines called antibiotics. Antibiotics are used to treat infections. <{(Invented) name}> is used to kill certain serious bacterial infections.

2. What you need to know before you use <{(invented) name}>

Do not use <{(Invented) name}>

If you have been told you are allergic (hypersensitive) to clindamycin (the active ingredient in <{(Invented) name}>), lincomycin (another antibiotic) or to any of the ingredients of <{(Invented) name}> (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking <{(Invented) name}>

- If you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using <{(Invented) name}> 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 up to several weeks after discontinuation of treatment.
- If you suffer from problems with your kidneys or liver.
- If you suffer from asthma, eczema or hayfever.

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.

Talk to your doctor, pharmacist or nurse if you develop any severe skin reactions or hypersensitivity to <{{(Invented) name}}> (listed in section 4).

If you have to take <{{(Invented) name}}> for a long time, your doctor may arrange regular liver, kidney and blood tests.

Long term use can also make you more likely to get other infections which do not respond to <{{(Invented) name}}> treatment. If this happens, please talk to your doctor as soon as possible.

Other medicines and <{{(Invented) name}}>

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

- Erythromycin, clarithromycin, telithromycin, rifampicin, antibiotics used to treat infections.
- Itraconazole, voriconazole, used to treat fungal infections.
- Ritonavir, cobicistat, used to treat HIV.
- St. John's wort (*Hypericum perforatum*), used to treat mild depression and anxiety.
- Carbamazepine, phenytoin and phenobarbital, used to treat epilepsy.
- Dihydroergotamine, ergotamine, used to treat migraine.
- Ergometrine, used during labor to reduce blood loss.
- Midazolam, triazolam, sedatives and sleep agents.
- Amiodarone, quinidine, used for irregular heartbeats.
- Cisapride, used to treat gastrointestinal disorders.
- Pimozide, used for mental health problems.
- Alfuzosin, used to treat benign prostate enlargement.
- Simvastatin, lovastatin, cholesterol-lowering drugs.
- Sildenafil, used to treat erection problems and high blood pressure in the lungs.
- Muscle relaxants used for operations or hospital procedures.
- 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.

<{{(Invented) name}}> with food and drink

The capsules may be taken either with or without food.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or think you might be pregnant you should contact your doctor before taking <{{(Invented) name}}>.

Breast-feeding

The active substance in this medicine may pass into breast milk. Ask your doctor or pharmacist for advice before taking <{{(Invented) name}}> whilst breast-feeding.

Driving and using machines

No effects have been reported on the ability to drive or use machines after taking <{{(Invented) name}}>.

<{(Invented) name}> contains lactose

Lactose, is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use <{(Invented) name}>

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

Adults and Elderly Patients

The recommended dose is 150 mg - 450 mg (1-3 capsules) every six hours, depending on the severity of your infection.

<{(Invented) name}> should always be swallowed whole with a full glass of water whilst in a upright position (i.e. sitting or standing).

Use in children

The recommended dose in children is between 3 and 6 mg per kg of body weight every six hours, depending on the severity of the infection. Your doctor will work out the number of capsules that your child should have.

If your child is unable to swallow capsules, talk to your doctor or pharmacist. Other forms of clindamycin may be more suitable.

If you take more <{(Invented) name}> than you should

If you accidentally take too many <{(Invented) name}> contact your doctor at once or go to the nearest hospital casualty department.

Take the labelled medicine package with you, whether there are any <{(Invented) name}> left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take <{(Invented) name}>

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

If you stop taking <{(Invented) name}>

If you stop taking the medicine too soon your infection may come back again or get worse. Do not stop taking <{(Invented) name}> unless your doctor tells you to.

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.

Tell your doctor immediately if you have any of the following side effects:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is a common side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation (pseudomembranous colitis). (common)

- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, throat or tongue, rash or itching (especially affecting the whole body). (Frequency is not known.)
- yellowing of the skin and whites of the eyes (jaundice). (Frequency is not known)
- Skin rashes which can be severe or life-threatening: (Frequency is not known)
 - a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals, known as Stevens-Johnson syndrome, or toxic epidermal necrolysis,
 - a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP),
 - skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - erythema multiforme)
 - widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
 - fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptoms).
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

Other possible side effects:

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

- diarrhoea
- stomach pain
- abnormal liver function test

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

- vomiting
- feeling sick
- smooth skin rash or redness covered by elevated bumps
- hives

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

- infection inside and around the vagina
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridium difficile*.
- effects on your blood system: reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- changes in the way things taste
- inflammation of the lining of the oesophagus (gullet), open sores or lesions in the lining of the oesophagus (gullet)
- yellowing of the skin and whites of the eyes (jaundice)
- red or scaly skin (exfoliative dermatitis), red measles-like rash (rash morbilliform), itching.

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 <{(Invented) name}>

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

Do not use <{(Invented) name}> after the expiry date which is stated on the carton and the blister foil. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from light.

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 <{(Invented) name}> contains

- The active substance is clindamycin hydrochloride equivalent to 150 mg of the active substance clindamycin.
- The other ingredients are:
 - Capsule contents: lactose monohydrate, maize starch, talc, magnesium stearate.
 - Shell: gelatine and titanium dioxide (E171)
 - Printing ink: Shellac, iron oxide black (E172), propylene glycol.

What <{(Invented) name}> looks like and contents of the pack

<{(Invented) name}> is white/white hard capsules with markings of 'CLIN 150' on the capsule body. They are available in blister packs of 24, 30, 32, 40 or 100 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]>

Distributed by:

<[To be completed nationally]>

This leaflet was last revised in 2025-05-13.

<Detailed information on this medicine is available on the web site of {name of Member State Agency (link)}>