

Package leaflet: Information for the patient

Clindamycin 150 mg hard capsules

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

1. What Clindamycin is and what it is used for

This medicine contains clindamycin which is an antibiotic used in the treatment of serious bacterial infections.

2. What you need to know before you take Clindamycin

Do not take Clindamycin:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin if you:

- have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines.
- suffer from problems with your kidneys or liver
- suffer from asthma, eczema or hayfever
- develop any severe skin reactions or signs of hypersensitivity, such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching, to Clindamycin

During treatment

If you develop severe or prolonged or bloody diarrhoea during or after using Clindamycin, tell your doctor immediately since it may be a sign of bowel inflammation (pseudomembranous colitis) which can

occur following treatment with antibiotics. You must not take medicines to prevent diarrhoea without first speaking to your doctor.

Your doctor may carry out regular checks to make sure that your liver and kidneys are working properly during treatment.

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.

Clindamycin does not get into the brain and is therefore not suitable for treating serious infections in and around the brain. Your doctor may need to give you another antibiotic if you have these infections.

Other medicines and Clindamycin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, or any of the following:

- antibiotics known as macrolides or streptogramin antibiotics e.g. erythromycin, virginiamycin, pristinamycin
- muscle relaxants used for operations
- 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
- CYP3A4 or CYP3A5 inducers like rifampicin may impact effectiveness of the medicine.

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.

Tell your doctor if you will be breast-feeding while taking Clindamycin as the active substance of this medicine may be passed into breast milk in small amounts. It is possible to breast-feed when taking this medicine. However, if your child has diarrhoea, blood in the stools, mouth or skin reactions see your doctor as soon as possible to have your treatment reviewed.

Driving and using machines

The effects on the ability to drive or use machines has not been established with clindamycin.

Clindamycin 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.

3. How to take Clindamycin

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

Adults and Elderly Patients

The recommended dose of Clindamycin is between 150 mg and 450 mg every 6 hours, depending on the severity of your infection.

Use in children and adolescents:

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

Method of administration

Clindamycin should be taken with a full glass of water. The capsules may be taken either before or after a meal. Clindamycin capsules are not suitable for children who are unable to swallow them whole.

Long term use of Clindamycin:

If you have to take Clindamycin for a long time, your doctor may arrange regular liver, kidney and blood tests. Do not miss these check-ups with your doctor.

Long term use can also make you more likely to get other infections that do not respond to clindamycin treatment.

If you take more Clindamycin than you should

If you accidentally take too many Clindamycin 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 capsules left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take Clindamycin

If the forgotten dose is just a few hours late, use 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 missed dose.

If you stop taking Clindamycin

If you stop taking the medicine too soon your infection may come back again or get worse.

Do not stop taking Clindamycin 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.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately. These side effects may need medical attention:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation or pseudomembranous colitis
- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips
- yellowing of the skin and whites of the eyes (jaundice).
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea
- Potentially life threatening skin rashes:

- 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 a more severe form with extensive peeling of the skin (more than 30% of the body surface) known as *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) and can be severe and life-threatening.

Other possible side effects may include:

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

- abnormal liver function tests (poor liver function)
- pain in the stomach / abdomen, diarrhoea

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

- feeling sick or being sick
- rash- characterized by a flat red area on the skin that is covered with small bumps, hives

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*.
- changes in the way things taste
- effects on the blood system: reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- inflammation of the lining of the oesophagus (gullet), open sores or lesions in the lining of the oesophagus (gullet)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin

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, blister and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Bottles: Use within 6 months of opening.

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 contains

The active substance is clindamycin. Each hard capsule contains 150 mg or 300 mg of clindamycin (as hydrochloride).

The other ingredients are silica, colloidal anhydrous; lactose monohydrate, see section 2 “Clindamycin contains lactose” maize starch, magnesium stearate; indigo carmine (E 132); titanium dioxide (E 171) and gelatin.

What Clindamycin looks like and contents of the pack

The 150 mg capsules are hard cylindrical gelatin capsules with a blue cap and a blue body.

The 300 mg capsules are hard cylindrical gelatin capsules with a blue cap and white body.

Clindamycin is available in blisters packs of 16 and 30 capsules (300 mg only), 24 capsules (150 mg only) and perforated unit dose blisters of 12 x 1 (150 mg only) and 16 x 1 capsules (300 mg only). Clindamycin 150 mg is also available in bottles of 100 capsules.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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