

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clindamycin 300 mg Capsules Clindamycin (as hydrochloride)

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 symptoms are the same as yours.
- If you get any of the 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 300 mg Capsules are and what they are used for
2. What you need to know before you take Clindamycin 300 mg Capsules
3. How to take Clindamycin 300 mg Capsules
4. Possible side effects
5. How to store Clindamycin 300 mg Capsules
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1. What Clindamycin 300 mg Capsules are and what they are used for

This medicine contains Clindamycin hydrochloride which is an antibiotic used to fight certain pathogens. It belongs to the group of lincosamides. Clindamycin 300 mg Capsules are used in cases of serious bacterial infections of the nose, throat, ears, airways, skin, skeleton, joints, sexual organs and digestive system.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Clindamycin 300 mg Capsules

Do not take Clindamycin 300 mg Capsules:

- if you are allergic to clindamycin or lincomycin which is a very similar antibiotic
- if you are allergic to any of the other ingredients of Clindamycin 300 mg Capsules (listed in section 6).

Warning and precautions

Take special care with Clindamycin 300 mg Capsules and consult your doctor:

Tell your doctor if you have any of the following conditions, to help him or her decide if Clindamycin 300 mg Capsules are suitable for you:

Talk to your doctor or pharmacist before taking Clindamycin 300 mg Capsules:

- 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 Clindamycin 300 mg Capsules stop taking the capsules and **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 even after 2 to 3 weeks following treatment with antibiotics.
- if you suffer from problems with your kidneys or liver.
- if you suffer from asthma, eczema or hay fever.
- If you develop any severe skin reactions or hypersensitivity to Clindamycin 300 mg Capsules
- if you are experiencing diarrhea or suffer from intestinal inflammatory disease.

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

When used for a long duration, Clindamycin 300mg Capsules may cause infections that cannot be treated with this antibiotic. Your doctor can explain the signs and symptoms of such types of infections.

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 300 mg Capsules

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:

- erythromycin (an antibiotic).
- muscle relaxants used for operations (neuromuscular blockers).
- 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.
- taking medicines such as rifampicin (an antibiotic), St. John's Wort (a herbal remedy), phenytoin (an anti-seizure medication) or carbamazepine (used to treat epilepsy or nerve pain) may reduce the effectiveness of Clindamycin Capsules.

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

Clindamycin 300 mg Capsules with food and drink

Clindamycin 300 mg Capsules should be swallowed whole with water and can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

You should contact your doctor or pharmacist before taking Clindamycin 300 mg Capsules if you are pregnant, or think you may be pregnant or are planning to become pregnant or breast-feeding.

Ask your doctor or pharmacist for advice **before** taking any medicine.

If you are pregnant or trying to become pregnant only use Clindamycin 300 mg Capsules if your doctor considers it to be necessary.

Breast-feeding

As Clindamycin 300 mg Capsules is excreted in human milk it should not be used during breastfeeding.

Driving and using machines

No effects on the ability to drive or use machines have been seen with Clindamycin.

Important information about some of the ingredients of Clindamycin 300 mg Capsules

Clindamycin 300 mg Capsules contain lactose monohydrate. Lactose monohydrate 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 take Clindamycin 300 mg Capsules

Always take Clindamycin 300 mg Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Clindamycin 300 mg Capsules should always be swallowed whole and washed down with a full glass of water.

Adults and elderly patients

The usual dosage is 150 - 450 mg every six hours (depending on the severity of your infection). Your doctor will tell you how many capsules to take. For dosages below 300 mg other clindamycin products are available.

Use in children

Your doctor will prescribe a lower dose.

The recommended dosage in children is between 12 - 24 mg/kg in 4 divided doses. Your doctor will work out the number of capsules your child should have.

The capsules should be swallowed whole with water and can be taken with or without food. Space the doses evenly through the day.

Long term use of Clindamycin 300 mg Capsules

If you have to take Clindamycin 300 mg Capsules 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 300 mg Capsules treatment.

If you take more Clindamycin 300 mg Capsules than you should

If you accidentally take too many capsules you should contact your doctor at once. If you cannot speak to your doctor go to your nearest hospital accident and emergency department. Always take your Clindamycin 300 mg Capsules package with you, whether there are Clindamycin 300 mg Capsules left or not. Do not take more capsules until your doctor tells you to.

Symptoms of overdose are nausea, vomiting and diarrhoea.

If you forget to take Clindamycin 300 mg Capsules

If you miss a dose, take it as soon as you remember. If it is nearly time to take the next dose miss out the dose you forgot. Take your next dose at the right time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Clindamycin 300 mg Capsules

Do not stop taking your capsules because you feel better, if you stop taking this medicine too soon your infection may come back again or even get worse.

Do not stop taking this medicine or alter the dose you are currently taking without seeing your doctor first. You should only stop taking your capsules if your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Clindamycin 300 mg Capsules can cause side effects, although not everybody gets them. If you experience any allergic reaction, stop taking your medicine and tell your doctor immediately.

Tell your doctor immediately if you develop:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur after 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, dizziness, swelling of eyelids, face, lips, throat or tongue, 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
- Potentially life threatening skin rashes:
 - blistering and peeling of large areas of skin, mouth, around the eyes or genitals
 - 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.
- Fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

The following side effects have also been known to occur following the use of Clindamycin:

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

- pain in the stomach pain / abdomen
- diarrhoea. If you get diarrhoea, increase the amount you drink. Do not take any medicines to stop your diarrhoea unless your doctor tells you to.
- inflammation which causes stomach pain and diarrhoea (colitis)
- abnormal liver function tests (poor liver function) (an assessment by your doctor is required).

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

- skin rash - characterized by a flat red area on the skin that is covered with small bumps, hives.
- Feeling sick or being sick (throwing up).

Frequency cannot be estimated from the available data:

- inflammation or ulcer of the oesophagus (food pipe).
- changes in your blood composition (an assessment by your doctor is required).
- intense itching and inflammation of the genital area, infection inside and around the vagina
- anaphylactic reactions (a type of severe allergic reaction)
- fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (Drug rash with eosinophilia and systemic symptoms) and can be severe and life threatening
- yellowing of the skin and whites of the eyes (jaundice).
- changes in the way things taste.
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips, skin rashes, intense itching.
- a more severe decrease in a specific class of white blood cell (agranulocytosis), a reduction in the number of white blood cells (leucopenia), a decrease in the number of white blood cells (neutropenia), a reduced number of platelets in the blood (thrombocytopenia), an increase in the number of white blood cells (eosinophilia)
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridium difficile*.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin 300 mg Capsules

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 300 mg Capsules after the expiry date which is stated on the carton and blister labels 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 300 mg Capsules contain

- The active substance is clindamycin hydrochloride. Each Clindamycin 300 mg Capsule contains 300 mg of clindamycin.
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate and talc.
- Capsule shell is made of gelatin. The colouring agents used in the capsule shell are patent blue V (E 131) and titanium dioxide (E 171).

What Clindamycin 300 mg Capsules look like and contents of the pack

Clindamycin 300 mg Capsules are powder blue. They come in packs of 4, 8, 16, 20, 24, 30, 32, 40 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

EG (Eurogenerics), Bus B22, Esplanade S N, Brussels, Brussels-Capital Region, 1020, Belgium

Manufacturer:

Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland.

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Centrafarm Services B.V., Van De Reijtsstraat 31-E, 4814 NE Breda, Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Clindamycine EG 300mg capsules, hard
Ireland:	Clindamycin 300 mg Capsules
Luxembourg:	Clindamycine EG 300mg gélules
The Netherlands:	Clindamycine CF 300 mg, capsules

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