



Package leaflet: Information for the patient

Clindamycin Hydrochloride 150 mg Capsules, hard

Clindamycin hydrochloride

The name of your medicine is Clindamycin Hydrochloride 150 mg Capsules, hard. It will be referred to a Clindamycin Capsules in this

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
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See

What is in this leaflet

- What Clindamycin Capsules are and what they are used for
- What you need to know before you take Clindamycin Capsules 3. How to take Clindamycin Capsules
- Possible side effects
- How to store Clindamycin Capsules
- Contents of the pack and other information

1. What Clindamycin Capsules are and what they are used for

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

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

Do not take Clindamycin Capsules

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

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Clindamycin 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 Capsules 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.
- you suffer from problems with your kidneys or liver.
- you suffer from asthma, eczema or hay fever.
- you develop any severe skin reactions or hypersensitivity to Clindamycin Capsules.

Clindamycin Capsules do not get into the brain and are 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.

If you have to take Clindamycin Capsules 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 Clindamycin Capsules treatment. If this happens, please talk to your doctor as soon as possible.

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 Capsules

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

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 used for operations (neuromuscular blockers).
- Oral contraceptive pills. You should use extra contraception such as condoms whilst taking Clindamycin Capsules and for seven days after taking Clindamycin Capsules.
- 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 this medicine.

Clindamycin Capsules with food and drink

The capsules may be taken either before or after a meal.

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 for advice before taking this medicine.

Tell your doctor if you will be breast-feeding while taking Clindamycin Capsules as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Clindamycin Capsules are appropriate for you. Although it is not likely that a nursing infant will take in very much of the active substance from the milk it drinks, if your baby gets bloodstained diarrhoea or shows any signs of illness, tell your doctor at once. You should stop breast-feeding if this happens.

Driving and using machines

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

Clindamycin Capsules contain lactose monohydrate

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 Capsules

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Capsules should always be swallowed whole and washed down with a full glass of water while in an upright position.

Adults and Elderly Patients

The recommended dose of Clindamycin Capsules is between 150 and 450 mg (1 to 3 capsules) every 6 hours, depending on the severity of your infection.

Size: 240 x 560 mm

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.

Long term use of Clindamycin Capsules If you have to take Clindamycin 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 Capsules treatment.

If you take more Clindamycin Capsules than you should

If you accidentally take too many Clindamycin Capsules 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 Capsules

If the forgotten dose is just a few hours late, use it straightaway. 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 Capsules

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

If you have any further questions on the use of this medicine, ask your doctor or 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 develop:

- 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).
- 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) know 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 look 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.

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, characterised by a flat red area on the skin that is covered with small 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 causes bruising or bleeding or weaken the immune system
- Changes in the way things taste

(rash morbilliform), itching

- 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

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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 Capsules

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and blister labels after the text "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Clindamycin Capsules contain

The active substance is clindamycin hydrochloride. Each capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

The other ingredients are lactose monohydrate, pregelatinised starch, purified talc and magnesium stearate.

Capsule: gelatin, titanium dioxide (E171) and water. Printing ink: Shellac, propylene glycol, black iron oxide (E172),

potassium hydroxide What Clindamycin Capsules look like and contents of the pack Clindamycin Capsules are white hard capsules with a marking of

Clindamycin Capsules 150mg are available in blister packs of 24 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder Somex Pharma, Ilford, Essex, IG3 8BS, UK.

Manufacturer

Somex Pharma, Ilford, Essex. IG3 8RA. UK.

This leaflet was last revised in 11/2023

Other sources of information:

To request a copy of this leaflet in braille or large print please call, 020 8590 9399 (UK Only).

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