

Clindamycin 150 mg Capsules

(Clindamycin 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 further questions, please ask your doctor or 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 Clindamycin Capsules are and what they are used for
2. What you need to know before you take Clindamycin Capsules
3. How to take Clindamycin Capsules
4. Possible side effects
5. How to store Clindamycin Capsules
6. Contents of the pack and other information



1 What Clindamycin Capsules are and what they are used for

Clindamycin is an antibiotic. Clindamycin Capsules are used to treat infections caused by certain types of bacteria only. In particular, the types of bacteria that cause infections of the skin, of the flesh immediately under the skin, of the bones, and bacteria that are often found in abscesses and in infections of the abdomen (belly) are sometimes treated with clindamycin.

2 What you need to know before you take Clindamycin Capsules

Do not take Clindamycin Capsules:

- If you or your child have or have ever had an allergic reaction to any medicines that contain clindamycin or another very similar antibiotic called 'lincomycin'.
- If you or your child have or have ever had an allergic reaction to any other ingredients in Clindamycin Capsules (see section 6, Contents of the pack and other information).
- If you or your child have diarrhoea.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Clindamycin Capsules if:

- you or your child have asthma, hay fever or eczema
- you or your child have kidney or liver problems
- you or your child have ever had inflammation of the large bowel (called colitis) with severe blood-stained diarrhoea in the past
- you or your child have ever had any other serious illness of the stomach or gut or bowels in the past
- you or your child 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 this medicine, 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 hayfever.
- you or your child develop any severe skin reactions or hypersensitivity to Clindamycin

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.

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.

Due to the risk of inflammation of the oesophagus (oesophagitis) and oesophageal ulcer, it is important to always take Clindamycin Capsules exactly as described in section 3.

Other medicines Clindamycin Capsules

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

You can take clindamycin with some antibiotics, but you should not take clindamycin if you are already taking a type of antibiotic called a macrolide (such as erythromycin, clarithromycin, azithromycin, or telithromycin) or streptogramin. Discuss this with your doctor if you are not sure.

Mockup for Ib Variation

If you go into hospital or attend a dentist for treatment, it is important to tell the doctor or dentist that you are taking Clindamycin Capsules as they may change the way some hospital medicines work. In particular, clindamycin can increase the effects of some medicines that are used in general anaesthetics (muscle relaxants).

If you are taking medicines for a condition called myasthenia gravis, clindamycin could stop them working as well as usual.

If you are taking oral contraceptive pills. You should use extra contraception such as condoms whilst taking this medicine and for seven days after taking it.

Clindamycin like other antibacterials may interfere with Oral Typhoid vaccine. To avoid this, clindamycin should not be taken 3 days before and after taking the Oral Typhoid vaccine. Discuss this with your doctor if you are not sure.

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.

If you are taking CYP3A4 or CYP3A5 inducers like rifampicin, these may impact the effectiveness of this medicine.

Pregnancy and breast-feeding

Consult your doctor before taking Clindamycin Capsules if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Clindamycin is not usually given to pregnant women unless it is really necessary. Your doctor will advise you if you really need to take clindamycin while you are pregnant. If possible, you should stop breast-feeding while you are taking clindamycin. If you cannot stop breast-feeding, you should take care to look at your baby's stools. If your baby gets diarrhoea, with or without blood in it, or shows any other signs of illness, tell your doctor immediately. 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

If you have been told by your doctor that you are intolerant to some sugars, ask your doctor for advice before taking this medicine.

Clindamycin capsules contain small amounts of ethanol (alcohol), less than 100 mg per dose.

3 How to take Clindamycin Capsules

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

You can take the capsules with or without food.

You should:

- swallow the capsules whole
- wash them down with a full glass of water
- space the doses evenly through the day
- avoid lying down for 30 minutes after taking each dose to avoid possible irritation of the oesophagus.

The daily dose depends on your illness. Your doctor will tell you how many capsules you should take and this will also appear on the pharmacy label on the pack. Follow the instructions carefully. Never change the dose your doctor has prescribed.

Adults and elderly people:

The recommended dose in adults and the older people is from 150 mg up to a maximum of 450 mg

(one to three capsules) every six hours, depending on the severity of the infection.

Children:

These capsules are not suitable for children who are too young to be able to take them whole. For children who can swallow capsules, the recommended dose is between 3 and 6 mg per kg every six hours, depending on the severity of the infection.

Your doctor will work out the right dose for your child's weight.

You should make sure that you take the capsules for the number of days that your doctor has told you to take them.

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 treatment.

If you take more Clindamycin Capsules than you should:

If you take too many capsules, you should tell your doctor at once. If you cannot speak to your doctor, go to the accident and emergency department in the nearest hospital. Remember to take the Clindamycin Capsules pack with you so they will know exactly what you have taken. Do not take any more Clindamycin Capsules until your doctor tells you to.

If you forget to take Clindamycin Capsules:

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 Clindamycin Capsules:

You should not stop taking the capsules before the end of the course just because you feel better because your infection may come back again or even get worse. You should only stop taking your capsules before finishing the course if 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.

If you experience any of the following serious side effects, stop taking your Capsules and tell your doctor immediately or go to the nearest hospital accident and emergency department.

- 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, dizziness, swelling of eyelids, tongue, throat, face or lips, rash or itching (especially affecting the whole body)
- 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) 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 (DRESS)), and acute generalised exanthematous pustulosis (AGEP)) 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 1 to 10 users in 100)

- stomach pain
- diarrhoea
- abnormalities in liver function tests and poor liver function

Uncommon (may affect 1 to 10 users in 1,000)

- feeling sick
- being sick
- reddening of the skin
- lumpy rash (hives)

Frequency not known (frequency cannot be estimated from the available data)

- impaired sense of taste
- throat ulcers
- sore throat
- infection inside and around the vagina
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridioides difficile*.
- changes in blood count including agranulocytosis (lack of white blood cells).
- blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely
- an increase in the number of blood cells called eosinophils. Some people who have this also have breathing problems
- widespread joint pain.
- 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.

* Side effects that are more likely to occur if Clindamycin capsules are taken in a lying position and/or without enough water.

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 Yellow Card Scheme (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 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. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not use Clindamycin Capsules if you notice any visible signs of deterioration such as a change in the colour.

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 to protect the environment.

6 Contents of the pack and other information

What Clindamycin Capsules contain:

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

The other ingredients are lactose monohydrate, maize starch, magnesium stearate, talc.

Capsule shell: Gelatin, azorubine (E122) and indigo carmine (E132).

Printing ink: Shellac, titanium dioxide (E171), propylene Glycol (E1520), ethanol.

What Clindamycin Capsules look like and contents of the pack:

Clindamycin 150 mg Capsules are lavender/maroon and are marked CL150.

Clindamycin Capsules are available in cartons containing 24 capsules and containers of 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:


The Marketing Authorisation Holder is Sandoz Limited
Park View, Riverside Way, Watchmoor Park,
Camberley, Surrey, GU15 3YL
United Kingdom

The Manufacturer is

Chanelle Medical Ltd., Loughrea, Co. Galway, Ireland.

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