

Package leaflet: Information for the user

Clindamycin 75mg Capsules, Hard Clindamycin 150mg Capsules, Hard Clindamycin 300mg Capsules, Hard

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, 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

The active substance of Clindamycin belongs to the group of antibiotics and it is 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 (hypersensitive) to Clindamycin, lincomycin or to any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Clindamycin 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 **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 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 and Clindamycin

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

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

Clindamycin with food, drink and alcohol

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

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or think you might be pregnant, you should contact your doctor **before** taking Clindamycin.

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

Breast-feeding

Tell your doctor if you will be breast-feeding while taking Clindamycin, as clindamycin may be passed into breast milk. Your doctor will decide if Clindamycin is 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.

Clindamycin Capsules contains lactose

Clindamycin Capsules contains lactose a type of sugar. If you have been told that you have 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 has told you. Check with your doctor or pharmacist if you are not sure.

Clindamycin Capsules should always be swallowed whole and washed down with a full glass of water while in an upright position & no less than 30 minutes before lying down to avoid possible irritation of the oesophagus. It can be taken with or without food, according to your preference. Do not crush the capsules.

Adults and Elderly Patients

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

Use in Children

This medicine is used for children who are able to swallow capsules. The recommended dose in children is between 12 and 25 mg / kg /day of bodyweight, divided into six hourly doses, depending on the severity of the infection. Clindamycin should be dosed based on total body weight regardless of obesity. 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.

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 have taken too many Clindamycin or if a child has accidentally taken 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 left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take Clindamycin

If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose.

Do not take a double dose to make up for a forgotten dose. If you are in doubt, always consult your doctor or pharmacist.

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.

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.

- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea
- Signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of the eyelids or face or lips or 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 (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) 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- characterized 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 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.

* 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 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

- 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 and blister labels. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- 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 capsules contain

The active substance is clindamycin hydrochloride.

Each 75 mg capsule contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

Each 150 mg capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

Each 300 mg capsule contains clindamycin hydrochloride equivalent to 300 mg of the active substance clindamycin.

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

75 mg capsule shell: gelatin, FD&C blue 1 (E133), D&C yellow 10 (E104).

150 mg capsule shell: gelatin, FD&C blue 1(E133), titanium dioxide (E171), D&C yellow 10 (E104).

300 mg capsule shell: gelatin, FD&C blue 1(E133) and titanium dioxide (E171)

Printing ink: shellac, potassium hydroxide and titanium dioxide (E171).

What Clindamycin Capsules looks like and contents of the pack

Clindamycin 75 mg capsules, hard are green transparent (body) / green transparent (Cap), size '3' hard gelatin capsule printed with 'M' on cap and '40' on body filled with white to off-white granular powder. Approximately 16 mm in length.

Clindamycin 150 mg capsules, hard are green transparent (body) / light blue opaque (Cap), size '2' hard gelatin capsule printed with 'M' on cap and '41' on body filled with white to off-white granular powder. Approximately 18 mm in length.

Clindamycin 300 mg capsules, hard are light blue opaque / light blue opaque, size '0' hard gelatin capsule printed with 'M' on cap and '42' on body filled with white to off-white granular powder. Approximately 21 mm in length.

Clindamycin 75 mg (150 mg and 300 mg) capsules, hard are available in blister packs of 6, 10, 12, 24, 30 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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