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Package Leaflet: Information for the user

Clindamycin 300 mg 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 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 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 300mg capsules, hard (called Clindamycin capsules in the rest of this leaflet) belong to a group of medicines called antibiotics. Antibiotics are used to treat infections. Clindamycin capsules are used to kill certain bacteria that can cause serious infections.

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 Capsules

Do not take Clindamycin Capsules

If you have been told you are allergic (hypersensitive) to clindamycin (the active ingredient in Clindamycin capsules), lincomycin (another antibiotic) or to any of the ingredients of Clindamycin capsules (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist 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 up to several weeks after discontinuation of treatment.
- If you suffer from problems with your kidneys or liver.
- If you suffer from asthma, eczema or hay fever.
- If you have been told by your doctor that you have an intolerance to some sugars.

Talk to your doctor, pharmacist or nurse if you develop any severe skin reactions or hypersensitivity to Clindamycin capsules. (listed in section 4).

If you have to take Clindamycin capsules for a long time, your doctor may arrange regular liver, kidney and blood tests.

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.

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.

Other medicines and Clindamycin Capsules

Some medicines can affect the way Clindamycin works, or Clindamycin itself can reduce the effectiveness of other medicines taken at the same time. Make sure your doctor knows if you are taking any medicines listed here:

- Erythromycin, an antibiotic used to treat infections.
- Muscle relaxants used for operations or hospital procedures.
- 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.

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 Capsules with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

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.

The effects of Clindamycin capsules on the unborn child are not known. 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. It is not likely that a nursing infant will take in very much of the active substance from the milk it drinks. However, 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 have been reported on the ability to drive or use machines after taking Clindamycin capsules.

Clindamycin capsules contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. How to take Clindamycin Capsules

Always use this medicine exactly as your doctor has told you. Check with your doctor 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 the elderly

One capsule every six hours.

Use in children

The usual 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

Your doctor will decide if you are taking Clindamycin capsules for a long time and 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 which 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. 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 Capsule

If you forget the dose 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 Capsule

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.

4. Possible side effects

Like all medicines, Clindamycin capsules can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have any of the following side effects

- 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 (pseudomembranous colitis). (common)
- 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). (Frequency is not known.)
- yellowing of the skin and whites of the eyes (jaundice). (Frequency is not known.)
- skin rashes which can be severe or life-threatening: (Frequency is not known)
 - a wide spread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals, known as Stevens-Johnson syndrome or toxic epidermal necrolysis, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
 - 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 a 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)
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

Other possible side effects may include effects on your:

- Common (may affect up to 1 in 10 people):
 - diarrhoea
 - stomach pain
 - abnormal liver function test
- Uncommon (may affect up to 1 in 100 people):
 - vomiting
 - feeling sick
 - smooth skin rash or redness covered by elevated 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

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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via The Yellow Card Scheme. Website: 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 Clindamycin capsules after the expiry date which is printed on the carton and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

The active substance is Clindamycin Hydrochloride.

Each capsule contains clindamycin hydrochloride equivalent to 300 mg clindamycin.

The other ingredients are:

Capsule contents: Lactose monohydrate, Pregelatinised starch, Purified talc, Magnesium stearate
Capsule shell: Gelatin, Purified water, Indigotine (E132), Titanium dioxide (E171), Erythrosine (E127)
Edible black printing ink: Shellac, Propylene glycol (E1520), Black Iron Oxide (E172), Potassium Hydroxide (E525), Purified Water

What Clindamycin capsules looks like and contents of the pack
Hard gelatin capsule, lavender cap and lavender body with a marking 'C300' on the body.

Transparent PVC/PVdC film and Aluminium foil. Pack sizes: 30, 60, 90 and 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Somex Pharma
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Manufacturer

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