

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, 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 sign of illness are the same as yours.
- If you get any side effects, talk to your doctors, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What it 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 Rivopharm capsules
3. How to use 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 300 mg 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 serious bacterial infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLINDAMYCIN CAPSULES

Do not use 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, 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 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 hayfever.

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.

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, including:

- 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.
- CYP3A4 or CYP3A5 inducers like rifampicin may impact effectiveness of the medicine.
- Oral contraceptive pills. You should use extra contraception such as condoms whilst taking Clindamycin capsules and for seven days after taking Clindamycin capsules.

Clindamycin capsules with food and drink

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 capsules.

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 capsules as clindamycin may be passed into breast milk. Your doctor will decide if Clindamycin capsules 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 have been reported on the ability to drive or use machines after taking Clindamycin capsules.

Clindamycin capsules contain lactose

Lactose 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 USE CLINDAMYCIN CAPSULES

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

Adults and Elderly Patients

Capsules should always be swallowed whole and washed down with a full glass of water while in an upright position. The recommended dose is one capsule every six hours.

Use in children

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.

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 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

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, 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 a common side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation (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, swelling of eyelids, face or 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 (jaundice).
- Skin rashes which can be severe or life-threatening:
 - 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.

Other possible side effects may include:

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.

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 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 this medicine out of the sight and reach of children.

Do not use Clindamycin capsules after the expiry date which is stated on the carton and the blister foil. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from light.

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 substance is clindamycin hydrochloride equivalent to 300 mg of the active substance clindamycin.
- The other ingredients are:
 - Capsule contents: lactose monohydrate, maize starch, talc, magnesium stearate.
 - Shell: gelatine and titanium dioxide (E171)
 - Printing ink: Shellac, iron oxide black (E172), propylene glycol.

What Clindamycin capsules look like and contents of the pack

Clindamycin capsules are white/white hard capsules with markings of 'CLIN 300' on the capsule body. They are available in blister packs of 20, 24, 28, 30, 32 or 100 capsules.

Not all pack sizes may be marketed

Marketing authorisation holder and Manufacturer

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