Package leaflet: Information for the user
Dalacin C® 75 mg Capsules
clindamycin

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Dalacin is and what it is used for
2. What you need to know before you take Dalacin
3. How to take Dalacin
4. Possible side effects
5. How to store Dalacin
6. Contents of the pack and other information

1. What Dalacin is and what it is used for

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

2. What you need to know before you take Dalacin

Do not take Dalacin
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 Dalacin 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 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 hay fever.
- you develop any severe skin reactions or hypersensitivity to Dalacin.

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 Dalacin C Capsules exactly as described in section 3.
Dalacin 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.

Other medicines and Dalacin
Tell your doctor or pharmacist or nurse if you are taking, 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 this medicine and for seven days after taking it.
• 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.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant or think you might be pregnant you should contact your doctor before taking Dalacin. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Tell your doctor if you will be breast-feeding while taking this medicine as clindamycin may be passed into breast milk. Your doctor will decide if Dalacin 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 Dalacin.

Dalacin Capsules contain lactose
Dalacin Capsules contain lactose, 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 take Dalacin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist or nurse if you are not sure.
Dalacin Capsules should always be swallowed whole with a full glass of water, no less than 30 minutes before lying down, to avoid a possible irritation of the oesophagus.

Adults and Elderly Patients
The recommended dose is between 150 and 450 mg (2 to 6 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 Dalacin
If you have to take this medicine 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 Dalacin treatment.

If you take more Dalacin Capsules than you should
If you accidentally take too many Dalacin 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 Dalacin Capsules left or not. Do not take any more capsules until your doctor tells you to.

If you forget to take Dalacin
If the forgotten dose is just a few hours late, use 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 missed dose.**

If you stop taking Dalacin
If you stop taking this medicine too soon your infection may come back again or get worse. Do not stop taking Dalacin unless your doctor tells you to. If you have any further questions on how to take this product, 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.
- 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).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome) (frequency not known [cannot be estimated from the available data]).
- 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 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 *Clostridioides 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)* including severe damage to the food pipe (necrotising oesophagitis), 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
- inflammation of blood vessels in the skin (cutaneous vasculitis)
- skin reaction characterised by symmetrical, sharply defined redness in the skin folds, particularly the buttocks, groin, and armpits (symmetrical drug-related intertriginous and flexural exanthema)

* Side effects that are more likely to occur if Dalacin C 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 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 Dalacin

- 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 foils after EXP. The expiry date refers to the last day of that month.
- Store below 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 Dalacin C Capsules contain
The active substance is clindamycin hydrochloride. Each capsule contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.
The other ingredients are lactose monohydrate, maize starch, talc, magnesium stearate.
Capsule: gelatin, indigo carmine (E132), quinoline yellow (E104) and titanium dioxide (E171).
Printing ink: shellac, soya lecithin, dimeticone (Antifoam DC 1510) and black iron oxide (E172).

What Dalacin C Capsules look like and contents of the pack
Dalacin C Capsules are hard capsules coloured green/white, with markings of 'CLIN 75' and 'Pfizer'. They are available in blister packs (aluminium foil/PVC) of 24 capsules and bottle packs (high density polyethylene or amber glass) of 24, 100 or 500 capsules.

Not all pack sizes may be marketed.

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