

Package leaflet: Information for the user

Dalacin® C 75 mg Capsules

clindamycin hydrochloride

PFIZER

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 Dalacin **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 Dalacin.

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:

- erythromycin (an antibiotic).
- muscle relaxants used for operations (neuromuscular blockers).
- oral contraceptive pills. You should use extra contraception such as condoms whilst taking Dalacin and for seven days after taking Dalacin.
- 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.

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 Dalacin as clindamycin may be passed into breast milk. Your doctor will decide if Dalacin is appropriate for you. If you continue to take Dalacin, you should stop breast-feeding.

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 contains lactose a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

Adults and Elderly Patients

The recommended dose of Dalacin is between 150 and 450mg (2 to 6 capsules) every 6 hours, depending on the severity of your infection.

Use in children

The recommended dose in children is between 3 and 6mg per kg of bodyweight 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 Dalacin

If you have to take Dalacin 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 the 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).
- 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.

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,

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 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. 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 Dalacin C Capsules after the expiry date which is stated on the carton and blister labels. 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 to 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 75mg of clindamycin.

The other ingredients are lactose, 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).

What Dalacin C Capsules look like and contents of the pack

Dalacin C Capsules are hard capsules coloured green/white and with markings of 'CLIN 75' and 'Pfizer'.

Dalacin C Capsules 75 mg are available in blister packs of 24 and 100 capsules.

Marketing Authorisation Holder

Pfizer Limited,
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If you have any comments on the way this leaflet is written, please contact Medical Information at Pfizer Limited in Walton Oaks, Tadworth, Surrey.

Tel: 01304 616161.

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