Package leaflet: Information for the patient
Dalacin® C 150 mg Hard Capsules
clindamycin (as 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 your 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, 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

This medicine contains clindamycin hydrochloride which is an antibiotic used in the treatment of serious bacterial 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 Dalacin

Do not take Dalacin:
- if you are allergic (hypersensitive) to clindamycin, lincomycin, soya, peanuts or to any of the other ingredients of this medicine (listed in section 6).
- if you are experiencing diarrhoea or suffer from intestinal inflammatory disease.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking 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 diarrhoea during or after using Dalacin stop taking the capsules and **tell your doctor immediately**. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur even after 2 to 3 weeks following treatment with antibiotics.
- if you suffer from problems with your kidneys or liver.
- if you suffer from asthma, eczema or hay fever.
- if you develop any severe skin reactions or hypersensitivity to Dalacin.
- if you have recently taken or been given a lincosamide medicine such as clindamycin, or a macrolide medicine such as erythromycin. This is important, because there is an increased chance that Dalacin will not work as well as it should.

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.

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.

When used for a long duration, Dalacin may cause infections that cannot be treated with this antibiotic. Your doctor can explain the signs and symptoms of such types of infections.

Other medicines and Dalacin
Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines. Some medicines can affect the way this medicine works, or this medicine itself can reduce the effectiveness of other medicines taken at the same time. These include:
- muscle relaxants used during operations.
- oral contraceptive pills. You should use extra contraception such as condoms whilst taking Dalacin C Capsules and for seven days after taking Dalacin C Capsules.
- 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.
- taking medicines such as rifampicin (an antibiotic), St. John's Wort (a herbal remedy), phenytoin (an anti-seizure medication) or carbamazepine (used to treat epilepsy or nerve pain) may reduce the effectiveness of Dalacin C Capsules.

Dalacin 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 may be pregnant or are planning to have a baby, you should contact your doctor, pharmacist or nurse **before** taking Dalacin. Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Breast-feeding
Tell your doctor if you are breast-feeding as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin is appropriate for you.

Driving and using machines
No effects on the ability to drive or use machines have been seen with Dalacin.

Dalacin Capsules contain lactose monohydrate and soya oil
Lactose monohydrate is 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.

Dalacin Capsules also contains soya oil. If you are allergic to peanut or soya, do not use this medicine.

3. How to take Dalacin

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure. Dalacin Capsules should always be swallowed whole and washed down with a full glass of water.

Recommended dose
Adults and Elderly Patients
The recommended dose of Dalacin is between 150 and 300 mg (1 to 2 capsules) every 6 hours, depending on the severity of your infection.

Children
This medicine is intended for children who are able to swallow capsules. The recommended dosage in children is between 12 - 24 mg/kg/day divided into 4 equal doses. Clindamycin should be dosed based on total body weight regardless of obesity. Your doctor will work out the number of capsules 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 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 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 forgotten 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 this medicine or alter the dose you are currently taking without seeing your doctor first.

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:
- 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).
- severe persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This may occur with some antibiotics and can be a sign of serious bowel inflammation or pseudomembranous colitis.
- potentially life-threatening skin rashes:
  – blistering and peeling of large areas of skin, mouth, around the eyes or genitals.
  – 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 (throwing up)
- 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*
- a more severe decrease in a specific class of white blood cell (*agranulocytosis*), a reduction in the number of white blood cells (*leucopenia*), a decrease in the number of white blood cells (neutropenia), a reduced number of platelets in the blood (thrombocytopenia), an increase in the number of white blood cells (eosinophilia)
- 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: HPRA Pharmacovigilance, website: www.hpra.ie. 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 labels after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine if you notice the capsules are cracked, soft or stuck together.

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 contains
The active substance is clindamycin. Each capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin base.

The other ingredients are: lactose monohydrate, maize starch, talc and magnesium stearate.
Capsule shell: gelatin and titanium dioxide (E171).
Printing ink: shellac, soya lecithin, dimeticone (antifoam DC 1510), black iron oxide (E172) and propylene glycol.

What Dalacin looks like and contents of the pack
Dalacin are hard gelatin capsules with an opaque white body and an opaque white cap containing a white to off-white powder.
Capsules are imprinted with ‘CLIN 150’ and ‘Pfizer’.

Dalacin is available in blister packs of 24 capsules.

Manufacturer
Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France.

Repackaged by
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