

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Dalacin® C Capsules 150 mg
Dalacin® C Capsules 300 mg
Capsules

Each capsule contains:

Clindamycin hydrochloride 150 mg, 300 mg

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

To treat infections caused by bacteria susceptible to clindamycin.

Therapeutic group:

Antibiotics from the lincosamide group.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

you are sensitive (allergic) to clindamycin, lincomycin or any of the other ingredients contained in the medicine (see section 6).
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Special warnings regarding use of the medicine

Before treatment with Dalacin C Capsules, tell your doctor if:

- you are suffering from diarrhea or generally suffer from diarrhea when you take antibiotics, or if you have ever suffered from gastric or intestinal problems.
- you are suffering, or have suffered in the past, from impaired function of the liver or kidneys.
- you are suffering from atopy (eczema, allergic rhinitis, asthma).

Additional warnings regarding use of the medicine:

- The use of the medicine, similarly to other antibiotics, may cause diarrhea due to Clostridium difficile infection (CDAD). Tell the doctor immediately if you develop severe or prolonged diarrhea during or after use of this medicine.
- Prolonged use may also increase the risk of developing other infections not responding to treatment with this medicine. Dalacin C does not penetrate the brain and is therefore not appropriate for treatment of severe infections in and around the brain. The doctor may prescribe you another antibiotic treatment for such infections.
- Due to the risk of esophagitis and esophageal ulcer, it is important to ensure compliance with the instructions for use (see Section 3 'How to use this medicine').

Children and adolescents

Upon administration of Dalacin C Capsules to children and adolescents, appropriate monitoring for activity of the body systems is recommended.

Tests and follow up

If you need to take the medicine for a prolonged period, your doctor may ask you to perform periodic blood tests, liver and kidney function tests and blood counts.

Patients over the age of 60 should be more closely monitored for the development of diarrhea and change in bowel movement frequency.

Drug interactions

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Muscle relaxants since Dalacin C may also have a similar effect.
- Medicines affecting the activity of CYP3A4 or CYP3A5 enzymes, since they may affect the medicine's concentration in the body.

Using this medicine and food

The medicine can be taken regardless of meals. Swallow the medicine with plenty of water (a full glass of water) to prevent possible esophageal irritation.

Pregnancy and breastfeeding

If you are pregnant or think you may be pregnant, consult with the doctor **before** taking this medicine. Inform the doctor if you plan to breastfeed during the course of treatment with Dalacin C Capsules, as the active ingredient may pass into breast milk and cause side effects in the baby.

Driving and using machines

No effect on the ability to drive or use machines has been observed when taking this medicine.

Important information about some of this medicine's ingredients

Dalacin C Capsules contains lactose. If you have been told by your doctor that you have intolerance to certain sugars, contact your doctor before using this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

Swallow the capsule whole, with a full glass of water and no less than 30 minutes before lying down. Do not open the capsule and disperse its content, since the effect of this mode of administration has not been examined.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forgot to take this medicine at the scheduled time, and only a few hours have elapsed, take a dose as soon as you remember. If it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a missed dose. Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor. Skipping doses or discontinuing the treatment prematurely may decrease the efficacy of the treatment and increase the likelihood that bacteria will develop resistance to medicines and will not be treatable by Dalacin C Capsules or other antibiotics in the future.

If you stop taking this medicine

If you stop taking the medicine prematurely, the infection may recur or worsen. Do not stop taking Dalacin C Capsules unless you have been instructed to do so by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dalacin C Capsules may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor immediately in case of:

- watery or bloody diarrhea (with or without abdominal cramps or fever). This is a side effect which may occur during treatment with the antibiotic or even 2 months or more after taking the last dose

of the antibiotic and may indicate a severe bowel infection. In such case, treatment discontinuation may be required.

- hypersensitivity reactions or anaphylactic shock – can be manifested by wheezing, difficulty breathing, dizziness, swelling of the eyelids, face or lips, tongue or throat, rash or itching (especially if widespread throughout the body). In such case, immediate treatment discontinuation is required.
- blistering and peeling of large areas of skin, fever, cough, feeling unwell, swelling of the gums, tongue or lips.
- yellowing of the skin and whites of the eyes (jaundice).

Additional side effects:

- itching, vaginal infection, angioedema, skin redness accompanied by peeling (exfoliative dermatitis), abnormal results in liver function tests, acute kidney injury, decrease in white blood cells, agranulocytosis, decrease in platelet number in the blood (thrombocytopenia), polyarthritis (a type of arthritis), abdominal pain, nausea, vomiting, diarrhea, esophagitis and esophageal ulcer (possible occurrence of esophagitis and esophageal ulcer, particularly if taken in a lying position and/or with a small amount of water), metallic taste in the mouth, urticaria, morbilliform rash, exhaustion, blurred feeling or change in the state of consciousness, appearance of sores in the mucous tissues, such as mouth and lips, appearance of a circular rash on the face, body or limbs.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Dalacin C Capsules 150 mg:

Lactose, gelatin, maize starch, talc, magnesium stearate and titanium dioxide (E171).

Dalacin C Capsules 300 mg:

Lactose, gelatin, maize starch, magnesium stearate, talc, titanium dioxide (E171), erythrosine (E127) and indigo carmine (E132).

Dalacin C Capsules contains lactose:

Dalacin C Capsules 150 mg: about 209.5 mg lactose.

Dalacin C Capsules 300 mg: about 254 mg lactose.

What the medicine looks like and contents of the pack:

Dalacin C Capsules 150 mg: a white, hard gelatin capsule, with "Pfizer" and "CLIN150" imprinted in black.

Dalacin C Capsules 300 mg: a purple, hard gelatin capsule, with "Pfizer" and "CLIN300" imprinted in black.

The medicine is available in packs of 16 and 100 capsules. Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Dalacin C Capsules 150 mg: 019.95.24895

Dalacin C Capsules 300 mg: 105.03.28594

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