

PACKAGE LEAFLET: INFORMATION FOR THE USER

DALACIN C 150 mg, capsules

DALACIN C 300 mg, capsules

Clindamycin HCl

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

What is in this leaflet

1. What DALACIN C Capsules is and what it is used for
2. What you need to know before you take DALACIN C CAPSULES.
3. How to take DALACIN C CAPSULES.
4. Possible side effects
5. How to store DALACIN C CAPSULES
6. Contents of the pack and other information.

1. WHAT DALACIN C CAPSULES IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: ANTIBACTERIAL ANTIBIOTICS belonging to the lincosamide family. (J: Anti-infectives), ATC code: J01FF01.

This medicine is indicated for the treatment of certain severe bacterial infections caused by microorganisms susceptible to this antibiotic.

This medicine is also indicated for the prevention of infective endocarditis during dental care and upper respiratory tract procedures performed on an outpatient basis in patients allergic to beta lactams (penicillins, cephalosporins).

Only use this medicine if you have a medical prescription for it (see Advice/Health education).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DALACIN C CAPSULES

Do not take DALACIN C capsules:

- if you are allergic to clindamycin, lincomycin or any of the other ingredients mentioned in section 6;
- in children aged under 6 years since they may choke on the capsule.

If you are unsure about anything, you must ask your doctor or pharmacist for advice

Warnings and precautions

Before taking this medicine, tell your doctor if you have:

- a history of allergy, particularly to antibiotics, or a history of asthma,
- hepatic insufficiency (liver disease).
- an intolerance to certain sugars.

Tell your doctor immediately if any of the following disorders occurs during treatment with DALACIN C, capsules:

Severe and sudden allergic reaction (anaphylactic reaction, Quincke's oedema).

Severe skin reaction (DRESS syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis).



There is a slight risk of severe allergic reaction, with the following symptoms: tightness in the chest, dizzy spells, sudden swelling of the face and neck, severe cutaneous rash. Stop taking DALACIN C, capsules if these symptoms occur, because they are potentially life-threatening, and contact your doctor immediately.

The occurrence early in treatment of redness spreading all over the body with pustules, together with a fever, would suggest a severe reaction known as acute generalized exanthematous pustulosis (see 4. Possible side effects); tell your doctor immediately because it means treatment must be discontinued; after such a reaction any further administration of clindamycin is contraindicated.

You may experience diarrhoea when taking antibiotics, including clindamycin, even several weeks after treatment. Tell your doctor immediately if your diarrhoea becomes severe or persistent, or if you notice blood or mucus in your stools. Clindamycin therapy should be discontinued immediately since the reaction may be life threatening. In that case, do not take any medicine to stop or slow down your intestinal transit.

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.

Laboratory tests will be carried out if you are prescribed this treatment for a long period.

Use of this medicine is not recommended in patients presenting with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases).

Talk to your doctor or pharmacist before taking DALACIN C, capsules.

Children

Not applicable.

Other medicines and DALACIN C capsules

Your doctor may need to take regular blood tests to check more frequently how well your blood can clot.

Topical gastrointestinal agents, charcoal and antacids (aluminium, calcium and magnesium salts), reduce the digestive absorption of this medicinal products taken simultaneously. As a precaution, these topical gastrointestinal agents or antacids should be taken 2 hours after any other medicinal product.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a doctor's prescription.

DALACIN C capsules with food, drink and alcohol

Not applicable.

Pregnancy breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

It is preferable as a precaution not to use this medicine during the first trimester of pregnancy. During the second and third trimesters of pregnancy, clindamycin can be used if your doctor decides the treatment is necessary.

If you discover you are pregnant while taking this medicine, contact your doctor rapidly. Only he/she is competent to decide whether you should continue taking the medicine or not.

Breast-feeding

This medicine is excreted in low concentrations in human breast milk. Breast-feeding is possible whilst taking this medicine. However, in cases of diarrhoea, blood in stools or cutaneous rashes in your child, consult your doctor as soon as possible to review your treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

DALACIN C is not expected to have deleterious effects on driving or using machines.

DALACIN C capsules contains lactose

3. HOW TO TAKE DALACIN C capsules

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

Posology

Always take this medicine exactly as your doctor has told you.

For information, the usual dose is:

Treatment of infections

- Adults: 600 to 2,400 mg/24 hours in 2, 3 or 4 doses.
- Children aged over 6 years: 8 to 25 mg/kg/24 hours in 3 to 4 doses.

Prevention of infective endocarditis

- Adults: 600 mg orally in the hour preceding the procedure.
- Children aged over 6 years: 15 mg/kg orally in the hour preceding the procedure.

Method and route of administration

Oral route.

Swallow the capsules whole with a large glass of water.

DALACIN C capsules are not for children unable to swallow them whole.

Administration frequency

- Treatment of infections: 2, 3 or 4 doses per day.
- Preventive treatment: 1 dose in the hour preceding the procedure.

Treatment duration

To be effective, this antibiotic must be taken regularly at the prescribed doses and for as long as the doctor has prescribed it.

The disappearance of fever or any other symptoms does not mean that you are completely cured.

Any possible impression of tiredness is not due to treatment with the antibiotic, but to the infection. Reducing or discontinuing treatment would have no effect on the impression and would delay your recovery.

If you have taken more DALACIN C capsules than you should have

Immediately contact your doctor or pharmacist.

If you forgot to take DALACIN C capsules

Treatment must be continued normally, leaving out the missing dose.

If you stop taking DALACIN C capsules

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can have side effects, although not everybody gets them.

Tell your doctor immediately if you develop:

- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

The frequency of the possible side effects listed below has been defined based on the following conventions:

Very common (affecting more than one in 10 patients)

Common (affecting between 1 and 10 in 100 patients)

Uncommon (affecting between 1 and 10 in 1,000 patients)

Rare (affecting between 1 and 10 in 10,000 patients)

Very rare (affecting fewer than 1 in 10,000 patients)

Common side effects:

- Inflammation of the intestines when used with antibiotics (pseudomembranous colitis),
- Diarrhoea, stomach pain,
- Modifications of hepatic tests (of the liver),

Uncommon side effects:

- Nausea, vomiting,
- Skin rashes that can take the form of papules and macules.
- Urticaria.

Side effects with unknown frequency:

- Drug-induced hypersensitivity reactions (severe, unpredictable allergic reaction caused by a medicine) including Quincke's oedema (sudden swelling of the face and neck) observed in patients who are allergic to penicillin,
- Severe cutaneous effects that may be fatal such as:
 - blisters and bubbles on the body, particularly around the mouth, nose, eyes and in the genital area (Lyell's and Stevens-Johnson syndromes),
 - skin rash that may be associated with fever, occurring suddenly and starting on the face or skin folds and that can get generalised (acute generalised exanthematous pustulosis),
 - or severe allergic reaction (drug hypersensitivity syndrome also called DRESS syndrome) possibly associating several symptoms such as fever, skin rash, increase in nodes size, serious fatigue, liver or kidney lesions and abnormal blood test results such as an increased number of certain white blood cells (eosinophilia),
- Redness of the skin (erythema), itching (pruritus), other cutaneous lesions (dermatitis exfoliative, dermatitis bullous, erythema multiform).
- Insufficient quantity of certain components of the blood (white blood cells, platelets), that may cause unexplained fever or small reddish-purplish spots on the skin (thrombocytopenic purpura),
- Increase in certain white blood cells (eosinophilia),
- Altered taste (dysgeusia),
- Inflammation of the mucous membranes of the oesophagus (oesophagitis and oesophageal ulcer),
- Yellow colouration of the skin, mucous membranes and white of the eye (jaundice),
- Infection of the vagina,
- Colitis associated with a *Clostridium difficile* infection.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DALACIN C CAPSULES

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 outer packaging.

Do not store above 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 150 mg, capsules contain



- The active substance is:

Clindamycin base 150.00 mg

In the clindamycin hydrochloride, hydrated form

Maize starch, talc, magnesium stearate, lactose monohydrate.

Composition of the capsule shell: gelatin, titanium dioxide.

What DALACIN C 300 mg, capsules contains

Clindamycin hydrochloride, hydrated form 339 mg

Quantity corresponding to clindamycin base 300 mg

For one capsule.

- The other ingredients are:

Maize starch, talc, magnesium stearate, lactose monohydrate.

Composition of the capsule shell: gelatin, titanium dioxide

What DALACIN C capsules look like and contents of the pack

The medicine is commercialised as capsules.

Dalacin C 150mg: Box of 12, 16 or 100 capsules.

Dalacin C 300mg: Box of 16 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder

PFIZER HOLDING FRANCE

23-25, AVENUE DU DOCTEUR LANNELONGUE

75014 PARIS

France

Manufacturer

FAREVA AMBOISE

ZONE INDUSTRIELLE

29 ROUTE DES INDUSTRIES

37530 POCE-SUR-CISSE

France

This leaflet was last revised on October 2021

Other

Not applicable.

ADVICE/HEALTH EDUCATION

Health education advice: WHAT YOU SHOULD KNOW ABOUT ANTIBIOTICS

Antibiotics are effective for the treatment of bacterial infections. They are not effective against viral infections.

Your doctor has chosen to prescribe you this antibiotic because it is appropriate for your specific case and your current illness.

Bacteria may survive or reproduce despite the action of an antibiotic. This phenomenon is called resistance: it causes some treatments by antibiotics to be ineffective.

Resistance increases with abusive or inappropriate use of antibiotics.

You may increase the risk of appearance of resistant bacteria and therefore delay your recovery or even cause this medicine to become ineffective if you do not respect the following:

- the dose to be taken,
- the times the doses should be taken,
- the treatment period.

Consequently, to preserve the efficacy of this medicine:

- 1. Only use an antibiotic if your doctor has prescribed it for you.**
- 2. Respect your prescription to the letter.**
- 3. Do not re-use an antibiotic without a medical prescription, even to treat a disease that appears similar.**
- 4. Never pass your antibiotic on to another person as it might not be appropriate for their illness.**
- 5. Once your treatment is finished, take all the opened boxes back to the pharmacy for appropriate and proper disposal of the medicine.**

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

**Council of Arab Health Ministers
Union of Arabic Pharmacists**