



DALACIN C 150 mg, capsules

DALACIN C 300 mg, capsules

Clindamycine 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.

In this leaflet:

1. WHAT DALACIN C CAPSULES IS AND WHAT IT IS USED FOR
2. 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. FURTHER INFORMATION

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

Pharmacotherapeutic class

Antibacterial antibiotic belonging to the Lincosamide family (J: Anti-infectives)

Therapeutic indications

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. BEFORE YOU TAKE DALACIN C CAPSULES

List of things to know before taking the medicine

If your doctor has informed you that you are intolerant to certain sugars, contact him/her before taking this medicine.

Contraindications

Do not take DALACIN C capsules:

if you are allergic to clindamycin, lincomycin or any of the other ingredients mentioned in section 6;

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

This medicine is contraindicated if you are breastfeeding (see [Pregnancy and breastfeeding](#)).

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).

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. 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. Do not take any medicine to stop or slow down your intestinal transit.

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.

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.

Interactions with food and drink

Not applicable.

Interactions with phytotherapy or other alternative medicines

Not applicable.

Use during pregnancy and breastfeeding

Pregnancy

It is preferable not to use this medicine during pregnancy. 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.

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

Breastfeeding

Breastfeeding is contraindicated during treatment with DALACIN C.

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

Sportsmen/women

Not applicable.

Effects on ability to drive or use machines

We don't expect DALACIN C to have deleterious effects on driving or using machines. Not applicable.

List of excipients with a notorious effect: lactose.

3. HOW TO TAKE DALACIN C capsules

Dosage

Always follow your doctor's prescription to the letter. For information, the usual dose is:

Treatment of infections

- Adults: 600 to 2400 mg/24 hours in 2, 3 or 4 doses.
- Children older than 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 older than 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.

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:

Contact your doctor.

If you forget to take DALACIN C capsules:

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

Risk of weaning syndrome

Not applicable.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DALACIN C capsules can have side effects, although not everybody gets them.

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 1000 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:
 - o blisters and bubbles on the body, particularly around the mouth, nose, eyes and in the genital area (Lyell's and Stevens-Johnson syndromes),
 - o 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),
 - o 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.

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. Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What DALACIN C 150 mg, capsules contains

The active substance is:

Clindamycin hydrochloride, hydrated form 177.515 mg

Quantity corresponding to clindamycin base 150.00 mg
For one capsule.

The other ingredients are:

Maize starch, talc, magnesium stearate, lactose.

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.

Composition of the capsule shell (lavender colour): indigo carmine, erythrosine, titanium dioxide, gelatin.

What DALACIN C capsules look like and contents of the pack

The medicine is commercialised as capsules.

Dalacin C 150mg: 12 or 100 capsules in heat-formed blister packs (Aluminium foil/PVC).

Dalacin C 300mg: 16 capsules in heat-formed blister packs (Aluminium foil/PVC).

Marketing authorisation holder

PFIZER HOLDING FRANCE

23-25, AVENUE DU DOCTEUR LANNELONGUE
75014 PARIS

Manufacturer

Fareva Amboise

Zone Industrielle
29 ROUTE DES INDUSTRIES
37530 POCE-SUR-CISSE
France

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AOVICE / HEALTH EDUCATION

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.

To report any side effect(s):	
Saudi Arabia: National Pharmacovigilance Center (NPC) Call NPC at 00966 11 2038222, Exts: 2317-2356-2353-2354-2334-2340 Toll-Free phone: 8002490000 Fax: +966 11 205 7662 E-mail: npc.drug@sfd.gov.sa Website: www.sfd.gov.sa/npc	United Arab Emirates (UAE): Website : www.moh.gov.ae Tel: 80011111, 0097142301448 Email: pv@moh.gov.ae P.O. Box 1853 Dubai
Iraq: Website: www.moh.gov.iq	Jordan: Website : www.jfda.jo Tel: 0096265632000 - 0096264602550 Fax:0096265105916 - 0096265105893 E-mail : info@jfda.jo
Kuwait: Website: www.moh.gov.kw/kdfc/ P.O. BOX: 22575, SAFAT 13086 KUWAIT	Lebanon : Website: www.moph.gov.lb
Oman: Web site: www.moh.gov.om Tel: 0096824601044 Fax: 0096824602287 E-mail: mohphar@omantel.net.om	Qatar: Website: www.sch.gov.qa E-mail: info@sch.gov.qa
Yemen: Website: www.sbd-ye.org Tel: 009671619174 Fax: 009671619173 E-mail: sbdma@y.net.ye	Syria: Website: www.moh.gov.sy
Iran: Website: www.behdasht.gov.ir/	

THIS IS A MEICAMENT

- 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