

DALACIN[®] C CAPSULES

Clindamycin hydrochloride (300 mg)

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What Dalacin C is used for

Dalacin C contains clindamycin hydrochloride, which is an antibiotic used in the treatment of serious bacterial infections. Its use should be reserved for people who are allergic to penicillin or for whom, in the judgment of the physician, a penicillin is inappropriate. It should be used only when other less toxic antibiotics are not effective.

How Dalacin C works

Dalacin C works by killing or stopping the growth of the bacteria causing your infection.

Before you use Dalacin C

- When you must not use it

Do not take Dalacin C if you are allergic (hypersensitive) to clindamycin, lincomycin or to any of the other ingredients in this medicine.

Pregnancy and lactation

If you are pregnant or think you might be pregnant, you should contact your doctor before taking Dalacin C. As clindamycin crosses the placenta, Dalacin C capsules should be used in pregnancy only if clearly needed.

Tell your doctor if you will be breast-feeding while taking Dalacin C. Breast-feeding is not recommended during administration of Dalacin C as this medicine may be passed into

breast milk. Dalacin C has the potential to cause serious side effects to the nursing infant such as diarrhea or blood in the stool, or rash. If Dalacin C is required, your doctor may suggest you an alternate medicine. Before taking the medicine, discuss with your doctor regarding the health benefits of nursing and the potential side effects of Dalacin C on the nursing child or from the underlying mother's condition.

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

- Before you start to use it

Tell your doctor if you have any of the following conditions to help him or her decide if Dalacin C is suitable for you:

- you have diarrhea or usually get diarrhea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhea during or after using Dalacin C, 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 have acute kidney injury.

If you develop any severe skin reactions or hypersensitivity to Dalacin C, stop taking the medicine and contact your doctor immediately.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines can affect the way Dalacin C works, or Dalacin C itself can reduce the effectiveness of other medicines taken at the same time. These include:

- muscle relaxants used during operations
- rifampicin, a medicine used to treat bacterial infections

How to use Dalacin C

- How much to use

To avoid the possibility of stomach and throat irritation, Dalacin C capsules should be taken with a full glass of water and no less than 30 minutes before lying down.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults and elderly patients

The recommended daily dose of Dalacin C is between 600 and 1800 mg divided in 2, 3 or 4 equal doses depending on the severity of your infection as determined by the doctor.

Children (over 1 month of age)

The recommended dose in children with serious infection is between 8 and 16 mg per kg per day in 3 or 4 equal doses. In more severe infections, the recommended dose is between 16 to 20 mg per kg per day in 3 or 4 equal doses.

Dalacin C capsules are not suitable for children who are unable to swallow them whole.

- When to use it

Use as directed by your doctor or pharmacist.

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Clindamycin hydrochloride (300 mg)

- How long to use it

Continue taking Dalacin C for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Dalacin C.

Tell your doctor immediately if you become pregnant while taking this medication.

Due to the risk of stomach and throat irritation, it is important to follow the administration guidance (see *How to use Dalacin C*).

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Dalacin C to anyone else, even if they have the same

symptoms or condition as you.

- Things to be careful of

Driving and using machines

The effect of Dalacin C on the ability to drive or operate machinery has not been evaluated.

Side Effects

Like all medicines, Dalacin C can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine.

Common side effects (affects $\geq 1/100$ to $< 1/10$ people):

- inflammation of the large intestine (pseudomembranous colitis)
- an increase in the number of eosinophils in the blood
- inflammation of vein due to blood clot
- diarrhea
- rash - characterized by a flat red area on the skin that is covered with small bumps
- abnormal liver function tests

If you develop severe or persistent diarrhea (watery or bloody) with or without abdominal pain, nausea, fever or vomiting, you may have *Clostridioides difficile* colitis (bowel inflammation). If this occurs, stop taking Dalacin C and contact your doctor immediately.

If you develop signs of a severe allergic reaction or severe skin reactions such as blister or peeling, Dalacin C should be discontinued and appropriate therapy should be initiated. It may be due to life-threatening conditions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP).

If you develop decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

You may develop inflammation/ ulcer from the throat to the stomach tube lining if you are taking this medicine in lying position and/or with a small amount of water.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my

[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Dalacin C

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

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

Product Description

- What it looks like

Clindamycin HCl 300 mg capsule is a white hard gelatin capsule filled with white powder marked "Clin 300" and "Pfizer".

Available in blister packs of 16 and 100 capsules.

- Ingredients

Active ingredient
Clindamycin hydrochloride.

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Clindamycin hydrochloride (300 mg)

Inactive ingredients

Maize starch, talc, magnesium
stearate and lactose monohydrate.

- MAL number:

Dalacin C Capsules 300 mg
MAL19985498ACZ

Manufacturer

Fareva Amboise
Pocé-sur-Cisse, France

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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