

PART III: PATIENT MEDICATION INFORMATION

PrDALACIN[®] C
(Clindamycin Hydrochloride Capsules)
clindamycin 150 mg, 300 mg

Read this carefully before you start taking DALACIN C and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about DALACIN C.

Antibacterial drugs like DALACIN C treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, DALACIN C should be taken exactly as directed. Misuse or overuse of DALACIN C could lead to the growth of bacteria that will not be killed by DALACIN C (resistance). This means that DALACIN C may not work for you in the future. Do not share your medicine.

What DALACIN C is used for?

DALACIN C is used:

- To treat serious infections caused by germs (bacteria).
- To help prevent serious infections during and after surgery.

How does DALACIN C work?

DALACIN C prevents the growth of germs causing your infection.

What are the ingredients in DALACIN C?

Medicinal ingredients: Clindamycin hydrochloride.

Non-medicinal ingredients:

- **150 mg:** cornstarch, lactose (256 mg), magnesium stearate, talc and sodium (0.3 mg).
Gluten-free.
- **300 mg:** cornstarch, lactose (294 mg), magnesium stearate, talc and sodium (<1 mmol).
Gluten-free.

DALACIN C comes in the following dosage forms:

150 mg and 300 mg capsules

Do not use DALACIN C if:

- You are allergic (hypersensitive) to
 - Clindamycin
 - Lincomycin
 - Other ingredients in the product (see list of non-medicinal ingredients)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DALACIN C. Talk about any health conditions or problems you may have, including if:

- You have a history of intestinal disorders such as colitis (inflammation of the colon), or inflammatory bowel disease.
- You have diarrhea or usually get diarrhea when you take antibiotics or have ever suffered from problems with your stomach or intestines (e.g. bowel disease, colitis).
- You suffer from problems with your kidneys or liver.
- You have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency and taking primaquine. You need to have routine blood tests while taking DALACIN C with primaquine to monitor for potential blood cell changes.
- You are pregnant or planning to become pregnant. Clindamycin passes to the human fetus.
- You are breastfeeding or planning to breastfeed.
- You have intolerance to some milk sugars. DALACIN C capsules contain lactose.

Other warnings you should know about:

Long term use of DALACIN C

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.

Taking DALACIN C with primaquine

Patients with G-6-PD deficiency taking the combination of clindamycin and primaquine should have routine blood examinations during therapy with primaquine to monitor for potential blood cell changes.

Breastfeeding

If you are breastfeeding or planning to breastfeed while taking DALACIN C, talk to your doctor. DALACIN C will pass through your breast milk to your baby. Your doctor will decide if you should take this medicine while breastfeeding. If your doctor has told you that you can take DALACIN C while breastfeeding, monitor your baby for possible side effects such as: diarrhea, mouth infection (thrush: white lesions in your baby’s mouth), diaper rash or blood in their stool. If your baby shows any signs, talk to your doctor and to your baby’s doctor.

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DALACIN C:

- Erythromycin (an antibiotic)
- Rifampin (an antibiotic)
- Muscle relaxants used for operations
- Aminoglycosides (a class of antibiotics)
- Primaquine (antimalarial)
- St. John’s Wort (*Hypericum perforatum*)

Tell your doctor if you are taking or being administered any other topical or oral medication, including erythromycin or neuromuscular blocking agents.

How to take DALACIN C:

Take your medicine (or give the medicine to your child) as your doctor has told you. If you are not sure, ask your doctor or pharmacist.

The capsules should be taken with a full glass of water to avoid throat irritation. The capsules can be taken with or without food.

Usual dose:

Treatment of infection:

Adult dose:

150 mg to 450 mg by mouth every 6 hours depending on the severity of infection.

Child dose (over 1 month of age and able to swallow capsules):

2 mg to 5 mg per kg every 6 hours depending on the severity of the infection.

Keep taking this medicine for the full time of treatment, even if you (or your child) begin to feel better after a few days.

Prevention of infection (patients undergoing surgery):

Adult dose:

300 mg by mouth at 1 hour before procedure; then 150 mg at 6 hours after the first dose.

Child dose (over 1 month of age and able to swallow capsules):

10 mg per kg by mouth at 1 hour before procedure; then 5 mg/kg at 6 hours after the first dose.

If you stop taking DALACIN C

If you stop taking the medicine too soon your infection may come back again or get worse.

Do not stop taking **DALACIN C** unless your doctor tells you to.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

Overdose:

If you think you have taken too much DALACIN C, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. This will help to keep a constant amount of medication in your blood. But, if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using DALACIN C?

DALACIN C can cause side effects such as:

- skin reddening, rash, itching, hives
- feeling sick, vomiting, diarrhea, stomach pain
- sore throat, throat sores
- low red blood cells (anemia) with symptoms such as bruising, bleeding
- low white blood cells (neutropenia) which can lead to more infections
- vaginal infection or vaginitis (inflamed vagina)

Contact your doctor immediately if the following happens:

- You have a severe allergic reaction with symptoms such as:
 - sudden wheeziness
 - difficulty in breathing
 - swelling of eyelids, face or lips
 - rash or itching (especially affecting the whole body)
- Blistering and peeling of large areas of skin
- Fever
- Cough
- Feeling unwell
- Swelling of the gums, tongue or lips
- You have liver problems with symptoms such as:
 - yellowing of the skin and whites of the eyes (jaundice).
- You have *Clostridium difficile colitis* (bowel inflammation) with symptoms such as:
 - severe, persistent watery or bloody diarrhea (watery or bloody) with or without
 - abdominal pain
 - nausea
 - fever
 - vomiting

This may happen months after the last dose of medication. If this occurs, stop taking the medication and contact your doctor right away.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Liver problem		√	√
COMMON Diarrhea Rash		√ √	
RARE Nausea, abdominal pain Vomiting Skin reactions : itching Signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)	√	√ √	√
NOT KNOWN <i>Clostridium difficile colitis</i> (bowel inflammation) with symptoms such as severe or persistent diarrhea, abdominal pain, nausea and vomiting.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your health care professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep in a safe place out of the reach and sight of children.

Store at room temperature (15°C to 30°C), away from heat and direct light.

Do not store in the fridge or freezer.

Do not store in the bathroom as moisture and heat can cause damage.

If you want more information about DALACIN C:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://www.canada.ca/en/health-canada.html>; the manufacturer's website (<http://www.pfizer.ca>), or by calling Pfizer Canada ULC at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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