

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDALACIN® C FLAVOURED GRANULES

Clindamycin palmitate hydrochloride for oral solution

This Patient Medication Information is written for the person who will be taking **DALACIN C FLAVOURED GRANULES**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **DALACIN C FLAVOURED GRANULES**, talk to a healthcare professional.

What DALACIN C FLAVOURED GRANULES is used for:

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

Antibacterial drugs like DALACIN C FLAVOURED GRANULES 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 FLAVOURED GRANULES should be taken exactly as directed. Misuse or overuse of DALACIN C FLAVOURED GRANULES could lead to the growth of bacteria that will not be killed by DALACIN C FLAVOURED GRANULES (resistance). This means that DALACIN C FLAVOURED GRANULES may not work for you in the future.

How DALACIN C FLAVOURED GRANULES works:

DALACIN C FLAVOURED GRANULES belongs to a class of medicines called antibiotics. It works by stopping the growth of the bacteria responsible for your infection.

The ingredients in DALACIN C FLAVOURED GRANULES are:

Medicinal ingredients: clindamycin palmitate hydrochloride.

Non-medicinal ingredients: artificial cherry flavour, ethyl paraben, pluronic F68, polymethylsiloxane, sucrose (when reconstituted with 75 mL of water, each 5 mL contains approximately 1837 mg of sucrose). Energy: 25.1 kJ (6 kcal)/5mL. Sodium: trace. Gluten-free.

DALACIN C FLAVOURED GRANULES comes in the following dosage forms:

Oral Solution 100 ml size: 75 mg clindamycin / 5 mL when reconstituted.

Do not use DALACIN C FLAVOURED GRANULES if:

- you have a history of allergies (hypersensitive) to
 - clindamycin
 - lincomycin

- other ingredients in the product (see **The ingredients in DALACIN C FLAVOURED GRANULES are**)

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

- have had stomach or intestinal problems such as:
 - colitis (inflammation of the colon)
 - inflammatory bowel disease
- have diarrhea or get diarrhea when you take antibiotics
- have kidney or liver problems
- have glucose-6-dehydrogenase (G-6-PD) deficiency and are taking primaquine. You need to have routine blood tests while taking DALACIN C FLAVOURED GRANULES with primaquine to monitor for potential blood changes.
- are pregnant or planning to become pregnant. DALACIN C FLAVOURED GRANULES can cross the placenta and harm your unborn baby.
- are breastfeeding or planning to breastfeed

Other warnings you should know about:

The medicine contains sucrose, so it is important to have good oral hygiene. Brush your teeth twice daily with toothpaste.

Breastfeeding:

If you are breastfeeding or planning to breastfeed while taking DALACIN C FLAVOURED GRANULES, talk to your healthcare professional. DALACIN C FLAVOURED GRANULES will pass through your breast milk to your baby. Your healthcare professional will decide if you should take this medicine while breastfeeding. If your healthcare professional has told you that you can take DALACIN C FLAVOURED GRANULES 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 healthcare professional and to your baby's healthcare professional.

***Clostridium difficile* colitis (bowel inflammation):**

DALACIN C FLAVOURED GRANULES can cause infections of the colon caused by a bacteria called *Clostridium difficile*. If you experience diarrhea or other symptoms of colitis, talk to your healthcare professional. See the Serious side effects and what to do about them table, below for more information about this and other serious side effects.

Long-term use of DALACIN C FLAVOURED GRANULES:

If you are going to be given DALACIN C FLAVOURED GRANULES for an extended period of time your healthcare professional will do blood tests to monitor your liver and kidneys. They will also check your red and white blood cells. It is important that you see your healthcare professional regularly. Long term use may make you more susceptible to other infections that do not respond to DALACIN C FLAVOURED GRANULES.

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 FLAVOURED GRANULES:

- other antibiotics used to treat bacterial infections, such as erythromycin, rifampin, aminoglycoside antibiotics
- muscle relaxants used during surgery
- primaquine, used to treat malaria
- St John's wort (*Hypericum perforatum*), an herbal medicine used to treat depression

How to take DALACIN C FLAVOURED GRANULES:

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

Usual dose:

Treatment of infection:

Child dose (over 1 month of age):

The daily dose is based on the body weight and the severity of the infection.

The daily dose is to be given to the child in divided doses every 8 hours or 6 hours.

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):

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

The medication can be taken with or without food.

Overdose:

If you think you, or a person you are caring for, have taken too much DALACIN C FLAVOURED GRANULES, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844-POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Possible side effects from using DALACIN C FLAVOURED GRANULES:

These are not all the possible side effects you may have when taking DALACIN C FLAVOURED GRANULES. If you experience any side effects not listed here, tell your healthcare professional.

DALACIN C FLAVOURED GRANULES can cause side effects such as:

- skin reddening, rash, itching, hives
- nausea, vomiting
- diarrhea
- stomach pain
- sore throat, throat sores

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Liver problems: yellowing skin or eyes, abdominal pain, nausea, vomiting, loss of appetite, dark urine, pale stool			√
Rare			
Acute generalized exanthematous pustulosis (AGEP): rash with small pustules, red and swollen skin, fever, itching, burning			√
Acute kidney failure (severe kidney problems): nausea, vomiting, fever, confusion, tiredness, swelling of extremities, urinating less or not at all, dark urine, thirst, shortness of breath, chest pain, seizures, coma			√
Drug reaction with eosinophilia and systemic symptoms (DRESS) (serious skin reactions that may affect one or more organs): fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine			√

Symptom / effect	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center, possibly swollen lips, mild itching or burning			√
Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside of the lips, mouth, nose, eyes and genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			√
Unknown			
Allergic reaction: swelling of face, lips, tongue or throat, difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, itching			√
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	
Clostridium difficile colitis (bowel inflammation): persistent or severe diarrhea, abdominal pain, nausea and vomiting			√
Kounis syndrome: a mixture of symptoms and signs of an allergic reaction and heart attack or unstable angina, with chest pain, shortness of breath, faintness, nausea, vomiting, fainting, itching, hives, sudden heavy sweating, unusual paleness, palpitations, hypotension, slow heartbeat			√
Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Vaginal infection (inflammation of the vagina or surrounding area):		√	

Symptom / effect	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
itching, burning, unusual or increased vaginal discharge			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Before reconstitution, store at controlled room temperature (20-25°C).

Do not refrigerate the reconstituted solution, since under conditions of low temperature, the solution may thicken and is difficult to pour.

The reconstituted solution is stable at room temperature for 14 days.

Keep out of the reach and sight of children.

If you want more information about DALACIN C FLAVOURED GRANULES:

- 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/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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