

## **PART III: PATIENT MEDICATION INFORMATION**

### **PrDALACIN<sup>®</sup> C FLAVOURED GRANULES** (Clindamycin Palmitate Hydrochloride for Oral Solution USP) 75 mg/5 mL clindamycin

**Read this carefully before you start taking DALACIN C FLAVOURED GRANULES 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 FLAVOURED GRANULES.**

**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.**

#### **What DALACIN C FLAVOURED GRANULES is used for?**

**DALACIN C FLAVOURED GRANULES is used:**

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

#### **How does DALACIN C FLAVOURED GRANULES work?**

DALACIN C FLAVOURED GRANULES prevents the growth of the germs (bacteria) responsible for your infection.

#### **What are the ingredients in DALACIN C FLAVOURED GRANULES?**

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 list of non-medicinal ingredients)

**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 intestinal disorders such as.
  - colitis (inflammation of the colon).
  - inflammatory bowel disease.
- have diarrhea or get diarrhea when you take antibiotics.
- suffer from problems with your stomach or intestines (e.g. bowel disease, colitis).
- suffer from problems with your kidneys or liver.
- 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. Clindamycin passes to the human fetus.
- are breastfeeding or planning to breastfeed. Clindamycin is passed to the infant through human breast milk. Because of the potential for serious adverse reactions in nursing infants, clindamycin should not be taken by nursing mothers.

**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.

**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:**

- 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 neuromuscular blocking agents.

**How to take DALACIN C FLAVOURED GRANULES:**

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.

**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 have taken too much DALACIN C FLAVOURED GRANULES, 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 FLAVOURED GRANULES?**

DALACIN C FLAVOURED GRANULES 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:
  - swelling of the lips, throat, face or eyelids
  - difficulty breathing
  - rash, itching, blistering and peeling skin
- 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 and contact your doctor right away.

- You have liver problems with symptoms such as:
  - yellowing of the skin or eyes
  - abdominal pain, nausea, vomiting

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b> <b>Liver problems</b> with symptoms such a yellowing skin or eyes, abdominal pain, nausea, vomiting		√	√
<b>COMMON</b> Diarrhea Rash		√ √	
<b><u>RARE</u></b> Skin reactions: itching	√		
<b>NOT KNOWN</b> <b>Serious allergic (hypersensitivity) reaction</b> with symptoms such as swelling of eyes, mouth, throat, difficulty breathing, blistering or peeling skin, rash, itching <b>Clostridium difficile associated disease</b> (bowel inflammation), with symptoms such as persistent or severe 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:**

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 PHOSPHATE:**

- 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 Inc. at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

Last revised: 11 June 2018