

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rDALACIN[®] C PHOSPHATE

Clindamycin Injection USP Sterile Solution

Read this carefully before you start taking **DALACIN C PHOSPHATE** 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 PHOSPHATE**.

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

What is DALACIN C PHOSPHATE used for?

DALACIN C PHOSPHATE is used for the treatment of serious bacterial infections.

How does DALACIN C PHOSPHATE work?

DALACIN C PHOSPHATE reduces the production of key proteins in germs. This prevents growth in germs and reduces the infection.

What are the ingredients in DALACIN C PHOSPHATE?

Medicinal ingredients: Clindamycin phosphate.

Non-medicinal ingredients: benzyl alcohol, disodium edetate, dilute hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), and sterilized water for injection.

DALACIN C PHOSPHATE comes in the following dosage forms:

DALACIN C PHOSPHATE is a clear, colourless solution. It is supplied in 2 mL, 4 mL and 6 mL vials of undiluted sterile solution.

Do not use DALACIN C PHOSPHATE 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 PHOSPHATE. 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.
- are pregnant or planning to become pregnant. Clindamycin passes to the human fetus.
- are breastfeeding or planning to breastfeed.
- You are taking primaquine for an enzyme deficiency called glucose-6-phosphate dehydrogenase (G-6-PD). You need to have routine blood tests, to monitor for potential blood cell changes.

Other warnings you should know about:

DALACIN C PHOSPHATE contains benzyl alcohol which may be harmful to newborns and children up to 3 years old.

Breastfeeding

If you are breastfeeding or planning to breastfeed while taking DALACIN C PHOSPHATE, talk to your doctor. DALACIN C PHOSPHATE 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 PHOSPHATE 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.

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 PHOSPHATE:

- Erythromycin (an antibiotic)
- Rifampin (an antibiotic)
- Muscle relaxants used during operations
- Primaquine (antimalarial)
- Aminoglycosides (a class of antibiotics)
- 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 PHOSPHATE:

The health care professional will administer DALACIN C PHOSPHATE and will:

- Decide whether the medicine should be:
 - injected into a vein or

- injected into a muscle
- Ensure that:
 - the medicine will be diluted before it is administered into a vein
 - medicine will not be diluted if administered into a muscle
 - the medicine will be given for the full treatment period
 - the medicine will be inspected to determine there is:
 - no discolouration
 - no leaks
 - no solid particles floating in solution
 - no haziness in the solution

Usual dose:

Your doctor will determine the dose and for how long you should receive it.

Long term use of DALACIN C PHOSPHATE:

- If you have to use 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 clindamycin treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much DALACIN C PHOSPHATE, contact a 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 PHOSPHATE?

These are not all the possible side effects you may feel when taking DALACIN C PHOSPHATE. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

DALACIN C PHOSPHATE can cause side effects such as:

- Skin reddening, rash, itching, hives
- throat ulcers, sore throat
- feeling sick, being sick
- stomach pain and diarrhea
- injection site irritation
- thrombophlebitis (inflammation of the vein due to blood clot)

- low red blood cells (anemia) with symptoms such as bruising, bleeding
- low white blood cells (neutropenia) which can lead to 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 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 problems with symptoms such a yellowing skin or eyes, abdominal pain, nausea, vomiting		√	√
COMMON			
Diarrhea		√	
Rash		√	
RARE			
Acute kidney failure (severe kidney problems): confusion; tiredness; swelling; urinating less or not at all; shortness of breath; chest pain, seizures, coma.			√
Skin reactions	√		

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	
Itching	√		
NOT KNOWN			
Clostridium difficile associated disease (bowel inflammation), with symptoms such as persistent or severe diarrhea, abdominal pain, nausea and vomiting			√
Injection site reactions with symptoms as pain, redness and skin irritation.	√		
Serious allergic (hypersensitivity) reaction with symptoms such as swelling of eyes, mouth, throat, difficulty breathing, blistering or peeling skin, rash, itching			√

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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:

- This medicine should be stored at room temperature (15 to 30°C)
- This medicine should not be refrigerated or frozen

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

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