

**PART III: PATIENT MEDICATION INFORMATION**

**PrDALACIN® VAGINAL CREAM**  
**Clindamycin vaginal cream, 20mg/g**  
 (as clindamycin phosphate)

Read this carefully before you start taking DALACIN VAGINAL CREAM 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 VAGINAL CREAM.

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

**What DALACIN VAGINAL CREAM is used for?**

DALACIN VAGINAL CREAM is used to treat your vaginal infection. The infection may cause a milky discharge and fishy odour from the vagina.

**How does DALACIN VAGINAL CREAM work?**

DALACIN VAGINAL CREAM works by stopping the growth of the germs (bacteria) causing your vaginal infection.

**What are the ingredients in DALACIN VAGINAL CREAM?**

Medicinal ingredients: Clindamycin phosphate.

Non-medicinal ingredients: benzyl alcohol, cetostearyl alcohol, cetyl palmitate, mineral oil, polysorbate 60, propylene glycol, purified water, sorbitan monostearate, and stearic acid.

**DALACIN VAGINAL CREAM comes in the following dosage forms:**

DALACIN VAGINAL CREAM (clindamycin phosphate vaginal cream), 20 mg clindamycin per gram, is available as a semi-solid white cream in 40g collapsible laminate tubes with 7 disposable applicators for intravaginal use. Each full applicator (one dose), contains 100 mg of clindamycin (as clindamycin phosphate) in 5 grams of cream.

**Do not use DALACIN VAGINAL CREAM if:**

- You are allergic (hypersensitive) to
  - Clindamycin
  - Lincomycin
  - Other ingredients in the product (see list of non-medicinal ingredients)
- You have a history of
  - regional enteritis
  - ulcerative colitis (inflamed bowel)
  - inflamed bowel (antibiotic-associated colitis)

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

- you are pregnant, or planning to become pregnant
- you are breast-feeding or plan to breast-feed

If DALACIN VAGINAL CREAM was prescribed by your doctor while breast-feeding, monitor your child for possible side effects such as diarrhea, mouth infection (thrush), diaper rash or blood in stool.

**Other warnings you should know about:**

While using DALACIN VAGINAL CREAM:

- Do not use condoms or vaginal contraceptive diaphragms for 3 days after you use this medicine.
- Do not engage in vaginal intercourse or use other vaginal products (such as tampons or douches).
- Do not start using this medicine if you have your period (menstruating). Wait until your period is finished.
- Do not use this medicine if you are pregnant or breast feeding unless your doctor has told you to.
- Avoid contact with the eyes. In case of contact, rinse thoroughly with tap water.

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 VAGINAL CREAM:**

- any other drug, including erythromycin.
- Muscle relaxant.

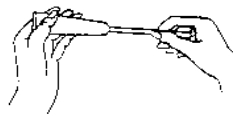
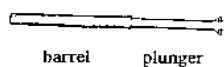
**How to take DALACIN VAGINAL CREAM:**

Use the plastic applicator to permit proper placement of the cream in the vagina.

Note: This cream is inserted into the vagina in much the same way as a tampon.

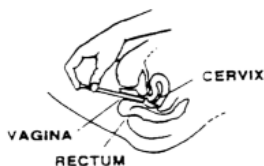
**Follow these steps to load the applicator;**

1. Remove the cap from the tube of cream.
2. Screw the open end of the applicator on the threaded end of the tube.
3. Gently squeeze the other end of the tube. This will push the cream into the barrel of the applicator. As the cream enters the barrel, the plunger will be forced outward. The applicator is full when the plunger stops.
4. Unscrew the applicator from the tube when the barrel is full.
5. Replace the cap on the tube of cream. Roll the tube from the bottom.



**Follow these steps to insert the vaginal cream;**

1. Stand, squat or lie on your back in a comfortable position.
2. Insert the loaded applicator gently into the vagina as far as it will comfortably go.



3. Hold the barrel of the applicator steady. Slowly press the plunger until it stops. This will deposit the cream in the vagina.
4. Remove the applicator and throw out. Remember to use a new applicator each and every time you insert this cream.

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

**Usual dose:**

Apply 1 applicator of cream intravaginally each night before you go to bed for 7 nights. Complete the entire 7 day treatment to help ensure treatment success.

There are 7 plastic applicators in the package. The applicator consists of both a plunger and a barrel. The tube of cream contains enough medicine to last for 7 days.

**Overdose:**

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

**Missed Dose:**

If you miss a dose one day, take the next dose the following day. Do not take extra doses.

**What are possible side effects from using DALACIN VAGINAL CREAM?**

The following side effects can occur:

- skin redness, itching, hives.
- indigestion, gas.

Contact your doctor if these symptoms become bothersome.

You may have *Clostridium difficile colitis* (bowel inflammation), if you have:

- severe bloody or watery diarrhea with or without:

- abdominal pain.
- nausea.
- fever.
- vomiting.

If this occurs, stop taking the medicine and contact your doctor right away.

Talk to your healthcare professional if you:

- develop a symptom not listed above.
- have any symptoms that interfere with daily activities.

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator  
1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

*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:**

Store at a temperature between 15°C and 25°C, away from heat and direct light.

Protect from freezing. Do not store in the fridge or freezer. Do not store in the bathroom as moisture and heat can cause damage.

Keep out of the reach and sight of children.

**If you want more information about DALACIN VAGINAL CREAM:**

- 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 contacting the distributor Paladin Labs Inc. at 1-888-867-7426 (Medical Information).

This leaflet was prepared by Pfizer Canada ULC

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