

Patient Information Leaflet

**DALACIN V Vaginal Cream
(Clindamycin Phosphate)**

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dalacin V is and what it is used for
2. What you need to know before you use Dalacin V
3. How to use Dalacin V
4. Possible side effects
5. How to store Dalacin V
6. Contents of the pack and other information

1. What Dalacin V is and what it is used for

What Dalacin V is

Dalacin V is a vaginal cream.

How Dalacin V works

Dalacin V contains clindamycin phosphate which is an antibiotic.

What Dalacin V is used for

Dalacin V is used for the treatment of bacterial vaginosis (a bacterial infection of the vagina). DALACIN V Vaginal Cream can be used to treat non-pregnant women and pregnant women during their second and third trimesters.

2. What you need to know before you use Dalacin V

Do not use Dalacin V

- if you are allergic to clindamycin, lincomycin or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer with regional enteritis, ulcerative colitis or a history of antibiotic-associated colitis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Dalacin V, if you have diarrhoea or usually get diarrhoea when you take antibiotics.

If you develop severe, prolonged or bloody diarrhoea during or after using Dalacin V tell your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

As with all vaginal infections, sexual intercourse during treatment with Dalacin V is not recommended.

Dalacin V may weaken condoms and diaphragms. Do not rely on condoms or contraceptive diaphragms when using this medicine.

The use of other vaginal products such as tampons or douches (vaginal washes) during treatment with the cream is not recommended.

Children

Dalacin V is not recommended for use in children.

Other medicines and Dalacin V

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Dalacin V may affect other medicines taken at the same time. Tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription or any other neuromuscular blocking agents.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, thinking that you might be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Breast-feeding

Tell your doctor if you will be breast-feeding while using Dalacin V as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin V is suitable for you. Although it is not likely that a nursing infant will take in very much of the active substance from the milk it drinks, if your baby gets bloodstained diarrhoea or shows any signs of illness, tell your doctor at once. You should stop breast-feeding if this happens.

Driving and using machines

No effects on the ability to drive or use machines have been seen with Dalacin V.

Dalacin V contains propylene glycol, cetostearyl alcohol and benzyl alcohol.

This medicine contains 250 mg propylene glycol in each 5 g applicator which is equivalent to 50 mg/g. This medicine contains 160.5 mg cetostearyl alcohol in each 5 g applicator, which is equivalent to 32.1 mg/g. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 50 mg of benzyl alcohol in each 5 g applicator which is equivalent to 10 mg/g. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Dalacin V

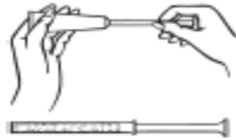
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one applicator full (approx. 5 grams), which should be placed into the vagina each night at bedtime for seven consecutive nights.

Your doctor may recommend a shorter, three day course of treatment depending on your symptoms. Always wash your hands before using the cream.

How Dalacin V is used

Insertion:



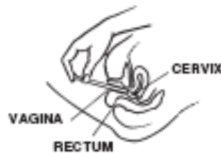
Remove the cap from the cream tube.

Screw one of the disposable plastic applicators supplied on to the tube where the cap has been removed. Rolling the tube from the bottom, squeeze gently and force the cream into the applicator.

When the plunger stops moving, the applicator is full.

Unscrew the applicator and replace the cap on the tube.

Lie on your back, firmly grasp the applicator barrel, and insert gently into the vagina as far as possible without causing discomfort. Still holding the barrel, slowly push the plunger until it stops and all the cream has been expelled.



Carefully withdraw the applicator and dispose of it. It is preferable to wrap it in paper before disposal in a waste container. Do not try to flush it down the toilet.

Wash your hands well after applying the cream.

If you use more Dalacin V than you should

Tell your doctor. Do not use any more cream until your doctor tells you to.

If you swallow Dalacin V

If you or somebody else swallows some Dalacin V contact your doctor. The cream is not likely to cause any harm but your doctor will be able to give you advice on what to do.

If you forget to use Dalacin V

If the forgotten dose is just a few hours late, use it straight away.

If it is nearly time for your next application, miss out the forgotten one. Do the next application at the normal time. Do not double the amount but carry on using your cream at the usual times.

If you stop using Dalacin V

Sometimes you may feel better after only a few days treatment. Even if you do feel better, do not stop using the cream until you have completed the full course of treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you:

- develop severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation (pseudomembranous colitis).
- experience an allergic reaction or skin reaction such as hives or a rash which is flat and raised bumps in tight clusters giving the skin a splotchy appearance.

The following adverse reactions and altered laboratory tests have been reported with the **oral or parenteral** use of clindamycin:

Infections and Infestations: Clostridioides difficile colitis

Gastrointestinal: Abdominal pain, esophagitis, nausea, vomiting, diarrhea, and pseudomembranous colitis.

Hematopoietic: Transient neutropenia (leukopenia), eosinophilia, agranulocytosis, and thrombocytopenia have been reported. No direct etiologic relationship to concurrent clindamycin therapy could be made in any of these reports.

Hypersensitivity Reactions: Maculopapular rash and urticaria have been observed during drug therapy. Generalized mild to moderate morbilliform-like skin rashes are the most frequently reported of all adverse reactions. Cases of Acute Generalized Exanthematous Pustulosis (AGEP), erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with clindamycin. A few cases of anaphylactoid reactions have been reported. If a hypersensitivity reaction occurs, the drug should be discontinued.

Liver: Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy.

Musculoskeletal: Cases of polyarthritis have been reported.

Renal: Acute kidney injury.

Immune System: Drug reaction with eosinophilia and systemic symptoms (DRESS) cases have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this table, please tell your doctor or pharmacist.

5. How to store Dalacin V

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Protect from heat, sunlight and freezing.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dalacin V contains

The active substance is clindamycin phosphate. Each gram of cream contains 20 mg of clindamycin.

The other ingredients are: Purified water, Mineral oil USP-viscosity 180, Stearic acid external use only, Propylene glycol USP, Benzyl alcohol, Cetostearyl alcohol NF, Sorbitan monostearate, Polysorbate 60 (food grade), Cetyl palmitate (cetyl ester wax). See section 2 “Dalacin V contains propylene glycol and cetostearyl alcohol.”

What Dalacin V looks like and contents of the pack

Dalacin V is a white, semi solid cream. It is supplied in 20 g tube with 3 disposable applicators.

Dalacin V/PIL/PK-01

According to Dalacin V/LPD/PK-01/approved USPI dated: May 26, 2022 & approved information in Pakistan

Marketed By:

Pfizer Pakistan Limited,
Karachi - Pakistan.