

## Package leaflet: Information for the user

# Dalacin® 2% Vaginal Cream

clindamycin

### 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 or your pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

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

### 1. What Dalacin Cream is and what it is used for

Dalacin Cream is a vaginal cream. It contains clindamycin phosphate which is an antibiotic. It is used in the treatment of bacterial vaginosis (a bacterial infection of the vagina).

### 2. What you need to know before you use Dalacin Cream

#### Do not use Dalacin Cream:

- If you are allergic (hypersensitive) to clindamycin, lincomycin, any antibiotics or any of the other ingredients in this medicine (listed in section 6).
- If you have, or have suffered from, inflammatory bowel disease including bowel inflammation following treatment with antibiotics (antibiotic-associated colitis).

### Warning and precautions

Talk to your doctor or pharmacist before using Dalacin Cream:

If you develop severe or prolonged or bloody diarrhoea when using Dalacin Cream or after treatment **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 Cream is not recommended. Some of the ingredients of Dalacin Cream may weaken condoms and diaphragms. Do not rely on condoms or contraceptive diaphragms for contraception or protection against sexually transmitted infections 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 and Elderly

Dalacin Cream is not recommended for children or in adults over 65 years of age.

### Other medicines and Dalacin Cream

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

Dalacin Cream should not be used during treatment with certain other antibiotics or some medicines used for general anaesthesia. Tell your doctor if you are taking other antibiotics or expect to undergo general anaesthesia.

### Pregnancy, breast-feeding and fertility

#### Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The use of Dalacin Cream in the first three months of pregnancy is not recommended as there is insufficient evidence of safety. If you are pregnant the cream should only be used after careful discussion with your doctor who will decide if this treatment is appropriate for you.

#### Breast-feeding

Tell your doctor if you will be breast-feeding as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin Cream is appropriate for you.

#### Fertility

Dalacin Cream is not known to have an effect on fertility. There is no evidence of impaired fertility or harm to foetus due to clindamycin.

### Driving and using machines

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

### Dalacin Cream contains benzyl alcohol, propylene glycol and cetostearyl alcohol

This medicine contains benzyl alcohol in each applicator. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains propylene glycol in each applicator.

This medicine contains cetostearyl alcohol in each applicator which may cause local skin reactions (e.g. contact dermatitis).

### 3. How to use Dalacin Cream

Always use Dalacin Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to use this cream.

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

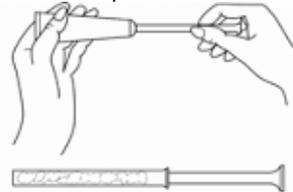
Your doctor may recommend a shorter, three day course of treatment depending on your symptoms.

Always wash your hands before using the cream.

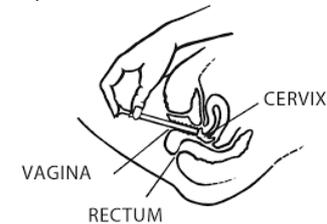
#### Insertion:

Remove the cap from the tube.

Screw one of the disposable plastic applicators supplied on to the tube where the cap has been removed. Holding 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 Cream than you should

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

#### If you swallow Dalacin Cream

If you or somebody else swallows some Dalacin Cream 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 Cream

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 use double dose to make up for the forgotten dose, but carry on using your Cream at the usual times.

#### If you stop using Dalacin Cream

Sometimes you may feel better after only a few days of 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 or pseudomembranous colitis.
- experience an allergic reaction or skin reaction such as hives or a measles-like rash. These are very rare side effects.

##### Very common: may affect more than 1 in 10 people

- vaginal thrush

##### Common: may affect up to 1 in 10 people

- fungal infections, yeast infection, inflammation or irritation of the vagina and vulva, painful urination (urinary tract or bladder infection),
- viral infections affecting the chest, throat, nose and head
- headache, dizziness, change of sense of taste
- stomach pain, constipation, diarrhoea, nausea (feeling sick), vomiting
- itching (non-application site), rash
- back pain
- excess of sugar in the urine, protein in the urine
- abnormal labour
- vaginal disorder, vaginal discomfort, vaginal discharge, irregular periods, abnormal bleeding from the uterus (metrorrhagia)

##### Uncommon: may affect up to 1 in 100 people

- allergic reaction (hypersensitivity)
- bacterial infection
- vaginal infection, inflammation or infection of the vagina (trichomonal vaginitis)
- a sensation of whirling and loss of balance (vertigo), nosebleed
- feeling bloated (indicating abdominal distension), flatulence (passing wind), bad breath
- rash, reddening of the skin, hives
- painful urination, excess of sugar in the urine, protein in the urine
- pelvic pain
- abnormal blood culture and sensitivity

##### Very rare: may affect up to 1 in 10,000 people (These side effects are associated with oral or injectable forms of clindamycin)

- a marked decrease in the number of blood cells which may cause bruising or bleeding or weaken the immune system (agranulocytosis), a slight decrease in the number of white blood cells (leucopenia or neutropenia), reduced blood platelet (thrombocytopenia)
- severe allergic reactions
- yellowing of the skin and whites of the eyes (jaundice).
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – (*toxic epidermal necrolysis*))
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – (*erythema multiforme*))

##### Not known: frequency cannot be estimated from the available data

- yeast infection (body)
- inflammation of the lining of large intestine (pseudomembranous colitis)
- nervousness, irritability, fatigue, muscle weakness (signs of possible overactive thyroid)
- ulcers, acid reflux disease, and irritable bowel syndrome (symptoms of gastrointestinal disorders)
- indigestion
- rash characterized by a flat, red area on the skin that is covered with small confluent bumps
- back pain
- growth of womb lining outside your womb (endometriosis)
- body pain, inflammation
- abnormal blood culture and sensitivity

##### Not known: frequency cannot be estimated from the available data

These side effects are associated with oral or injectable forms of clindamycin

- fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptoms) can be severe and life-threatening. The symptoms of DRESS usually begin several weeks after exposure to Clindamycin.

- a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Dalacin Cream

- 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.
- Do not store above 25 °C. Do not freeze.
- 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 protect the environment.

#### 6. Contents of the pack and other information

##### What Dalacin Cream contains

The active substance is clindamycin. Each gram of cream contains 20 mg or 2.0 % w/w of clindamycin (as clindamycin phosphate). The other ingredients are: benzyl alcohol (E 1519), sorbitan stearate (Type I), polysorbate 60, propylene glycol (E1520), stearic acid, cetostearyl alcohol, cetyl palmitate, mineral oil (viscosity 180) and purified water. (see section 2 "Dalacin Cream contains propylene glycol, cetostearyl alcohol and benzyl alcohol").

##### What Dalacin Cream looks like and contents of the pack

Dalacin Cream is a white, semi solid vaginal cream. It is supplied in a laminated tube. Each pack contains a tube containing 40 g of cream and seven vaginal applicators in a plastic canister.

##### Manufacturer

Dalacin Vaginal Cream sourced from the Czech Republic: is manufactured by Pfizer Manufacturing Belgium N.V., Puurs, Belgium or Pfizer Service Company, Zaventem, Belgium.

Dalacin Vaginal Cream sourced from Greece: is manufactured by Pfizer Service Company BVBA, Zaventem, Belgium.

##### Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

##### Parallel Product Authorisation number: PPA 465/416/1

Dalacin is a registered trademark of PFIZER INC.

This leaflet was last revised in February 2022.