

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Dalacin® 2% Vaginal Cream

clindamycin phosphate 2%

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is intended for treatment of bacterial vaginal infections, if bacteria susceptible to clindamycin have been identified.

Therapeutic group:

Lincosamide antibiotics.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient clindamycin or to lincomycin or to any of the other ingredients in this medicine (see section 6).
- you suffer or have previously suffered from inflammatory bowel disease or antibiotic-associated colitis (inflammation of the colon).

Special warnings regarding use of the medicine

Tell your doctor before using this medicine 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 2% Vaginal Cream, contact your doctor immediately since it may be necessary to stop 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 2% Vaginal Cream is not recommended. Dalacin 2% Vaginal Cream may decrease the effectiveness of condoms or diaphragms. Do not rely on condoms or contraceptive diaphragms to prevent pregnancy when using this medicine. The use of other vaginal products such as tampons or douches (vaginal washes) during treatment with Dalacin 2% Vaginal Cream is not recommended.

Children and adolescents

There is no information regarding the safety and effectiveness of using Dalacin 2% Vaginal Cream in children and adolescents.

Other medicines and Dalacin 2% Vaginal Cream

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Neuromuscular blockers, because Dalacin 2% Vaginal Cream may enhance the action of these medicines.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Breastfeeding

Tell your doctor if you will be breastfeeding while using Dalacin 2% Vaginal Cream, as the active ingredient in this medicine may pass into breast milk. Your doctor will decide if Dalacin 2% Vaginal Cream is suitable for you. Although it is not likely that a nursing baby will take in much of the active ingredient from the milk it drinks, if your baby has bloody diarrhoea or shows any signs of illness, tell the doctor at once. You should stop breastfeeding if this happens.

Driving and using machines

The effect of Dalacin 2% Vaginal Cream on driving or use of machines has not been examined.

Important information about some of this medicine's ingredients

This medicine 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 local irritation.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only. The standard dosage is usually:

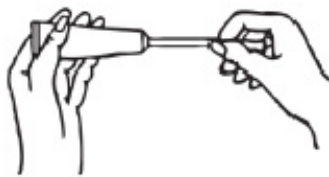
one applicator full of cream (approximately 5 grams). The cream should be inserted into the vagina each evening at bedtime for 3-7 consecutive nights.

Always wash your hands before using the cream.

Do not exceed the recommended dose.

For vaginal use, do not swallow.

How to use



Applicator

Remove the cap from the tube.

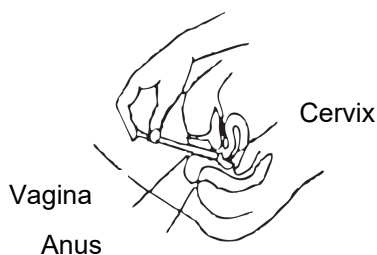
Screw one of the disposable applicators on to the tip of the tube where the cap has been removed.

Hold the tube from the bottom, squeeze gently to 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 and gently insert the applicator into the vagina as far as possible without causing discomfort. While still holding the applicator, 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 the applicator in paper before disposal in a waste bin. Do not discard the applicator in the toilet.

Wash your hands well after using the preparation.

If you have accidentally used a higher dosage of Dalacin 2% Vaginal Cream

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

If you have swallowed Dalacin 2% Vaginal Cream

If you or somebody else swallows some Dalacin 2% Vaginal Cream, contact the doctor. The cream is not likely to cause any harm, but your doctor will be able to advise you on what to do.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to use Dalacin 2% Vaginal Cream

If the forgotten dose is just a few hours late, use it straight away. If it is nearly time for your next dose, skip the forgotten dose. Apply the next dose at the normal time. Carry on using your cream at the usual times but do not use a double dose.

Adhere to the treatment as recommended by your doctor.

If you stop using Dalacin 2% Vaginal Cream

Sometimes you may feel better after only a few days of treatment. Even if your health improves, do not stop using the cream until you finish the treatment.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dalacin 2% Vaginal Cream may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Contact your doctor immediately if you:

- develop severe, persistent or bloody diarrhoea (which may be accompanied by stomach pain or fever). This is an uncommon side effect which may occur after antibiotic treatment and can be a sign of severe 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.

Very common side effects – affecting more than 1 in every 10 patients:

- Vaginal thrush (a yeast infection that causes soreness and itching around the vagina and vulva).

Common side effects – affecting less than 1 in every 10 patients:

- Fungal infection (candida), can cause red, itchy rashes
- Headache, dizziness
- Change to sense of taste
- Cough, cold, sore throat
- Stomach-ache
- Difficulty or delay emptying bowels
- Diarrhoea
- Nausea
- Vomiting
- Itchy skin
- Rash
- Back pain
- Urinary tract infection: bacterial infection of the urinary system, symptoms may include pain or burning while passing urine, needing to pass urine suddenly or more urgently than usual, needing to pass urine more often than usual during the night, urine looking cloudy, has a strong smell or blood in urine, lower tummy pain, back pain or pain under ribs.
- Increased levels of sugar and protein in the urine, signs may include urinary tract infections, foamy or frothy appearance of urine
- Abnormal labour
- Vaginal pain and swelling
- Abnormal bleeding, pain, or stress during your period (menstrual disorder)

- Vaginal discharge

Uncommon side effects – affecting less than 1 in every 100 patients:

- Bacterial infection
- Over-reaction of the immune system (hypersensitivity)
- A sensation of whirling and loss of balance
- Nosebleed
- Upset stomach
- Bad breath
- Passing wind
- Reddening of the skin
- A nettle-like rash, hives
- Painful urination
- Vaginal infection
- Pelvic pain
- Abnormal laboratory test results

Additional side effects of unknown frequency that may appear:

- White discharge or patches usually within folds of skin with itching, irritation and sometimes soreness (fungal infection ('candida') of skin)
- Overactive thyroid gland which can cause increased appetite, weight loss or sweating
- Bowel disorders
- Inflammation of the lining of large intestine causing severe diarrhoea with blood in stools (pseudomembranous colitis)
- Indigestion
- Rash with red spots
- Pain in women's lower tummy or back, usually worse during a period (endometriosis)
- Body pain
- Swelling

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Mineral oil (liquid paraffin), polysorbate 60, propylene glycol, cetostearyl alcohol, mixed fatty acid esters (cetyl palmitate)/cutina CP, stearic acid, sorbitan monostearate, benzyl alcohol, purified water.

What the medicine looks like and contents of the pack:

The package includes a tube that contains 40 grams of white cream and seven single-use applicators.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
064.17.27818

Revised in 11/2022 according to MOH guidelines.