

PACKAGE LEAFLET: INFORMATION FOR THE USER

PFIZER

Dalacin® Cream 2%

clindamycin phosphate

Read all of this leaflet carefully before you start using this medicine

- 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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

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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. Before you use Dalacin Cream

Do not use Dalacin Cream

If you are allergic (hypersensitive) to clindamycin, lincomycin or to any of the other ingredients in this cream. Do not use if you suffer with a history of inflammatory bowel disease or antibiotic-associated colitis.

Take special care with Dalacin Cream

Before taking this medicine make sure that your doctor knows if you have diarrhoea or usually get diarrhoea when you take antibiotics. If you develop severe or prolonged or bloody diarrhoea during or after using Dalacin Cream 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.

Dalacin cream is not recommended for use in children.

As with all vaginal infections, sexual intercourse during treatment with Dalacin Cream is not recommended. Dalacin Cream may weaken condoms and diaphragms. Do not rely on condoms or contraceptive diaphragms when using this medicine for 72 hours following treatment.

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

Taking other medicines

Dalacin Cream may affect other medicines taken at the same time.

Please tell your doctor if you are taking erythromycin (an antibiotic) or have recently taken any other medicines including medicines obtained without a prescription.

Warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.

Pregnancy

The use of Dalacin Cream in the first three months of pregnancy is not recommended as there is insufficient evidence of safety.

Tell your doctor before using this medicine if you are pregnant or think you may be pregnant. 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 while using Dalacin Cream as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin Cream 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 Cream.

Important information about some of the ingredients of Dalacin Cream

Dalacin Cream contains propylene glycol and cetostearyl alcohol which may cause local skin irritation and inflammation.

3. How to use Dalacin Cream

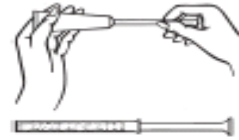
Always use Dalacin Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to use this cream.

The 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.

Insertion:



Remove the cap from the tube.

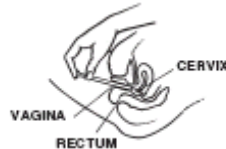
Screw one of the disposable plastic applicators supplied on to the tube where the cap has been

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 miss a dose of 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 the amount but carry on using your Cream at the usual times.

If you stop taking Dalacin Cream

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 how to take this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dalacin Cream 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.
- experience an allergic reaction or skin reaction such as hives or a measles-like rash. These are very rare side effects.

Very common side effects (likely to occur in more than 1 in 10 patients)

- Effects on your genital area: irritation of the vagina or cervix

Uncommon side effects (likely to occur in less than 1 in 100 patients):

- **Effects on your nervous system:** dizziness, vertigo, headaches.
- **Effects on your stomach and intestines:** heartburn, nausea (feeling sick), vomiting, diarrhoea, stomach pain and constipation.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dalacin Cream

- Keep out of the reach and sight of children.
- Do not use Dalacin Cream after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not freeze.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Dalacin Cream contains

- The active substance is clindamycin phosphate. Each gram of cream contains 20mg of clindamycin.
- The other ingredients are: benzyl alcohol, sorbitan stearate, polysorbate 60, propylene glycol, stearic acid, cetostearyl alcohol, cetyl palmitate, liquid paraffin and water.

What Dalacin Cream looks like and contents of the pack

Dalacin Cream is a white, semi solid cream. It is supplied in a laminated tube. Each tube contains 7.8 g, 20g or 40g of cream, packed in a cardboard carton together with the leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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