

Package leaflet: Information for the user

Dalacin 100 mg Vaginal Ovule

Clindamycin phosphate equivalent to 100 mg 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto 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 is and what it is used for
2. What you need to know before you use Dalacin
3. How to use Dalacin
4. Possible side effects
5. How to store Dalacin
6. Contents of the pack and other information

1. What Dalacin is and what it is used for

The name of your medicine is Dalacin 100 mg Vaginal Ovule. It is called 'Dalacin' in this leaflet.

Dalacin is a semi solid pessary (vaginal suppository). When inserted into the vagina it releases a medicine called clindamycin phosphate. This belongs to a group of medicines called 'antibiotics'.

Dalacin is used in the treatment of a bacterial infection of the vagina called bacterial vaginosis.

2. What you need to know before you use Dalacin

Do not use Dalacin

- If you are allergic to clindamycin, another antibiotic called lincomycin or to any of the other ingredients of this medicine (listed in section 6)
- If you have previously had inflammation of the colon (colitis) when taking antibiotics

Warnings and precautions

Talk to your doctor or pharmacist before using Dalacin

- if you have diarrhoea or usually get diarrhoea when you take antibiotics
- if you have a history of inflammatory bowel disease such as Crohn's Disease or Ulcerative Colitis

If you develop severe or prolonged or bloody diarrhoea during or after using Dalacin consult 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.

Please discuss with your doctor if you can use this medicine if the following apply:

- if you suffer from problems with your kidney, liver or immune system
- if you are under 16 years old or over 65 years old.

Dalacin is not to be used in children under 16 years old.

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

Other medicines and Dalacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if you are taking.

- Medicines to relax your muscles as Dalacin may increase the action of such medicines.

Pregnancy, breast-feeding and fertility

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

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

If you are pregnant Dalacin should only be used after careful discussion with your doctor who will decide if this treatment is appropriate for you.

If you are breast-feeding your doctor will decide if Dalacin is appropriate for you as the active substance may be passed into human milk.

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

This medicine is not likely to affect you being able to drive and use machines.

3. How to use Dalacin

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

Do not use this product if the foiled pouches containing vaginal ovules are torn, opened, or incompletely sealed.

Care should be taken to ensure that the ovule is not heated, since heat may soften and deform it. The recommended dose of this medicine is one ovule placed high into the vagina each night at bedtime for three consecutive nights. After insertion the ovule will melt and disappear.

Insertion:

- Remove the ovule from the aluminium foil pack.
- Lie on your back with your knees drawn up to your chest.
- Insert the ovule into the vagina with the tip of your third (middle) finger as far as possible without causing discomfort.

Always wash your hands after using the ovules.

If you use more Dalacin than you should

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

If you miss a dose of Dalacin

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

If it is nearly time for your next ovule, miss out the forgotten one. Take your next ovule at the normal time.

Carry on using your ovules at the usual times.

If you swallow Dalacin

If the ovule is eaten or swallowed contact your doctor. The ovules are not likely to cause any harm but your doctor will be able to give you advice on what to do.

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 inflammation of the lining of large intestine (pseudomembranous colitis).
- experience very severe allergic reaction or skin reactions. These are very rare side effects.

Common: (may affect up to 1 in 10 people)

- fungal infections, yeast infection
- headache
- stomach pain, diarrhoea, nausea (feeling sick)
- itching (non-application site)
- vaginal thrush, vaginal discomfort, vaginal disorder

Uncommon: (may affect up to 1 in 100 people)

- vomiting
- rash
- upper stomach or back pain
- fever or chills, feeling sick (malaise)
- painful urination, blood in the urine, cloudy or foul-smelling urine, increased frequency or urgency of urination
- vaginal infection, vaginal discharge, irregular periods
- pain (application site), itching, localized swelling

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

5. How to store Dalacin

- 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 carton and blister labels after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.

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 contains

- The active substance is clindamycin phosphate. Each ovule contains clindamycin phosphate equivalent to 100 mg of clindamycin.
- The other ingredient is hard fat.

What Dalacin looks like and contents of the pack

Dalacin is a white to off-white pessary. It is supplied in laminated foil pouches of 3 ovules packed in a box.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland,
9 Riverwalk, National Digital Park, Citywest Business Campus,
Dublin 24,
Ireland.

Manufacturer:

Pfizer Service Company BV
Hoge Wei 10, Zaventem
B-1930
Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Dalacin vaginal ovule
Italy	Cleocin
Germany	Sobelin 100 mg Vaginalzäpfchen
Spain	Dalacin 100 mg óvulus
Finland, Sweden	Dalacin

This leaflet was last revised in MM/YYYY.

Ref: DA 7_0