

## Package leaflet: Information for the patient

### Clindavasin V 20 mg/g 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 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 Clindavasin V vaginal cream is and what it is used for
2. What you need to know before you use Clindavasin V vaginal cream
3. How to use Clindavasin V vaginal cream
4. Possible side effects
5. How to store Clindavasin V vaginal cream
6. Contents of the pack and other information

#### **1. What Clindavasin V vaginal cream is and what it is used for**

Clindavazin V vaginal cream contains the antibiotic clindamycin. It is used to treat bacterial vaginosis (bacterial infections of the vagina).

#### **2. What you need to know before you use Clindavasin V vaginal cream**

##### **Do not use Clindavasin V vaginal cream if**

- if you are allergic to clindamycin or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to lincomycin;
- if you have a history of inflammatory bowel disease or colitis associated with the use of antibiotics.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Clindavazin V vaginal cream:

- If you have previously had diarrhea or colitis after taking another antibiotic, tell your doctor;
- If severe or prolonged diarrhea occurs during treatment with Clindavazin V, the medicine should be stopped and appropriate diagnostic procedures and treatment provided;
- Tell your doctor if you suffer from inflammatory bowel disease, such as Crohn's disease or ulcerative colitis;
- You may need to have some tests done before or after starting treatment with Clindavazin V to determine the exact cause of the infection;
- During treatment with Clindavazin V you should avoid sexual contact and do not use other vaginal products (such as tampons or lavage);
- Clindavazin V contains ingredients that can reduce the strength of condoms and vaginal diaphragms and make them less effective as methods of preventing pregnancy or sexually transmitted diseases. The use of condoms and diaphragms is not recommended until 72 hours after administration of Clindavazin V;

- The use of Clindavazin V, like other antibiotics, may lead to overgrowth of non-susceptible microorganisms, including fungi.

### **Children**

The use of Clindavazin V in children is not recommended as the safety and efficacy of this medicine in them have not been established.

### **Other medicines and Clindavazin V vaginal cream**

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

Tell your doctor if you are taking:

- muscle relaxants used for surgery (neuromuscular blockers) - clindamycin may increase their action.
- warfarin or similar medicines used to thin the blood - you are more likely to bleed. Your doctor may need to perform regular blood tests to check how well your blood is clotting.

### **Pregnancy, breast-feeding and fertility**

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

Clindavazin V vaginal cream should not be used to treat pregnant women during the first trimester of pregnancy.

Clindavazin V vaginal cream can be used to treat pregnant women during the second and third trimesters of pregnancy, as well as in lactating women, only in cases of proven need.

It is not known whether clindamycin can pass into breast milk in humans after vaginal administration. When administered orally or by injection, clindamycin may be excreted in human breast milk and may cause adverse reactions in the infant, such as diarrhea, blood in the stool or rash. Your doctor will decide whether to stop breast-feeding or to stop taking the medicine because of the risk of side effects for your baby.

### **Driving and using machines**

There are no data on the adverse effects of Clindamycin V on the ability to drive and use machines.

### **Clindavazin V vaginal cream contains cetostearyl alcohol, propylene glycol, benzyl alcohol and liquid paraffin**

Cetostearyl alcohol may cause local skin reactions (eg contact dermatitis).

One complete applicator of Clindavazin V (approximately 5 g of vaginal cream) contains 1 g of propylene glycol. Propylene glycol may cause skin irritation.

One complete applicator of Clindavazin V (approximately 5 g of vaginal cream) contains 50 mg of benzyl alcohol. Benzyl alcohol may cause mild local irritation and allergic reactions.

In addition, Clindavazin V vaginal cream contains liquid paraffin, which lowers the strength of latex or rubber products, such as condoms or vaginal diaphragms, so that their integrity may be affected. The use of these products is not recommended until 72 hours after treatment with Clindavazin V vaginal cream.

## **3. How to use Clindavazin V vaginal cream**

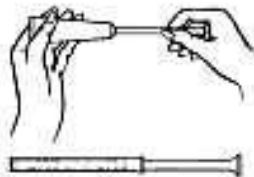
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

*Adults and adolescents over 16 years*

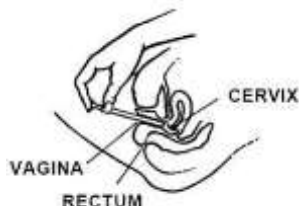
The recommended dose is one full applicator (approximately 5 g cream corresponding to 100 mg clindamycin) daily. It is applied in the vagina, preferably at bedtime. The duration of therapy is 3 to 7 consecutive days, as prescribed by your doctor depending on your symptoms.

#### Instructions for use

- Always wash your hands before using the cream.
- Remove the cap from the tube.
- Screw one of the disposable plastic applicators, placed in the package, in place of the cap with light pressure. Squeeze the tube at the bottom slightly and slowly pull the piston to the end position to fill the applicator. When the piston stops moving, the applicator is full.



- Unscrew the applicator and place the cap on the tube.
- Lie on your back, hold the applicator firmly and insert it gently into the vagina as far inward as possible without feeling discomfort. Holding the applicator, slowly push the piston until it stops moving and the entire amount of cream is pushed out.



- Carefully remove the applicator and discard it. It is preferable to wrap it in paper before throwing it away. Do not throw it in the toilet bowl.
- Wash your hands thoroughly after the procedure.

#### **If you use more Clindavazin V vaginal cream than you should**

If you use more than you should, please contact your doctor.

#### **If you forget to use Clindavazin V vaginal cream**

Continue treatment as usual. Do not use a double dose to make up for a forgotten dose.

#### **If you stop using Clindavazin V vaginal cream**

If you stop treatment, the desired effect will not be achieved or the symptoms may worsen again. Consult your doctor before stopping 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.

Contact your doctor **immediately** if:

- severe, persistent or bloody diarrhea appears (which may be associated with stomach pain or fever). This is an uncommon side effect that may occur during or after completion of antibiotic treatment and may be a sign of severe inflammation of the gut (pseudomembranous colitis).
- an allergic reaction with a rash and itching appears (especially affecting the whole body).

The following side effects are possible with treatment with this medicine:

Very common side effects (may affect more than 1 in 10 people):

- Fungal infection of the external genitalia and vagina (vulvovaginal candidiasis).

Common side effects (may affect 1 to 10 in every 100 people):

- Fungal infection, candidiasis of the body;
- Headache, dizziness, altered taste;
- Infection of the upper respiratory tract;
- Stomach pain and cramps, diarrhea, nausea, vomiting, constipation;
- Itching (unrelated to the site of application), rash;
- Back pain;
- Urinary tract infection, sugar in the urine, protein in the urine;
- Complicated birth;
- Inflammation of the external genitalia and vagina (vulvovaginitis), vulvovaginal disorder, itching and irritation of the external genitalia, menstrual disorders, pain in the external genitalia and vagina, uterine bleeding unrelated to the menstrual cycle (metrorrhagia), vaginal current.

Uncommon side effects (may affect between 1 and 10 in every 1,000 patients):

- Bacterial infection;
- Allergic reaction;
- Dizziness;
- Bleeding from the nose;
- Abdominal pain, bad breath, gas, bloating, dyspepsia, heartburn;
- Hives, redness of the skin (erythema);
- Burning and pain when urinating;
- Inflammation of the vagina (trichomoniasis vulvovaginitis), vaginal infection, pelvic pain;
- Deviations in microbiological examination.

Adverse reactions of unknown frequency (cannot be estimated from the available data):

- Fungal skin infection (candidiasis);
- Increased thyroid function (hyperthyroidism);
- Pseudomembranous colitis (severe inflammation of the intestines), gastrointestinal complaints;
- Skin rash with small, flat and raised red spots (maculopapular rash);
- Condition with severe pain before menstruation, infertility, menstrual disorders (endometriosis);
- Inflammation, pain, edema.

Reporting of side effects

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

Bulgarian Drug Agency  
8 Damyan Gruev Street  
1303 Sofia  
Tel.: +35 928903417  
Website: [www.bda.bg](http://www.bda.bg)

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

## **5. How to store Clindavazin V vaginal cream**

Keep out of reach of children.

Store below 25<sup>0</sup>C.

Do not freeze.

Shelf life after first opening the container: 7 (seven) days.

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

Do not dispose of medicines in the sewage system or in the household waste container. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

### What Clindavazin V vaginal cream contains

- The active substance is clindamycin as clindamycin phosphate. 1 g of vaginal cream contains 20 mg of clindamycin.
- The other ingredients are: benzyl alcohol, sorbitan stearate, polysorbate 60, propylene glycol, stearic acid, cetostearyl alcohol, cetyl palmitate, liquid paraffin, purified water, sodium hydroxide (for pH adjustment).

### What Clindavazin V vaginal cream looks like and contents of the pack

Homogeneous cream with white to almost white color.

Aluminum tube with HDPE screw cap containing 40 g Clindavasin V 20 mg / g vaginal cream.  
One tube with a patient leaflet and seven disposable applicators, packed in a cardboard box.

### **Marketing Authorisation Holder**

Antibiotic-Razgrad AD  
Office 201, 68 “Aprilsko vastanie” Blvd.  
7200 Razgrad, Bulgaria

### **Manufacturer**

Balkanpharma-Razgrad AD  
68 “Aprilsko vastanie” Blvd.  
7200 Razgrad, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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