

## **Package leaflet: Information for the user**

### **Clindavasin D 10 mg/ml cutaneous solution**

clindamycin phosphate

#### **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 Clindavasin D is and what it is used for
2. What you need to know before you use Clindavasin D cutaneous solution.
3. How to use Clindavasin D cutaneous solution
4. Possible side effects
5. How to store Clindavasin D cutaneous solution
6. Contents of the pack and other information

#### **1. What Clindavasin D is and what it is used for**

Clindavasin D cutaneous solution contains the antibiotic clindamycin. It is used to apply to the skin to treat acne.

#### **2. What you need to know before you use Clindavasin cutaneous solution**

##### **Do not use Clindavasin cutaneous solution**

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

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

Talk to your doctor or pharmacist before using Clindavasin D cutaneous solution:

- If you usually get diarrhoea or colitis after the administration of another antibiotic, inform your doctor;
- If severe or prolonged diarrhoea occurs during treatment with Clindavasine D cutaneous solution, talk to 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;
- Inform your doctor if you suffer from an 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 Clindavasin D cutaneous solution to determine the exact cause of the infection;
- The use of Clindavasin D cutaneous solution, like other antibiotics, can lead to an overgrowth of insensitive microorganisms, including fungi;
- The skin solution has an unpleasant taste, so caution is needed when applying it to the mouth area;

### **Other medicines and Clindavasin D cutaneous solution**

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 muscle relaxants used for surgery (neuromuscular blocking agents)- clindamycin 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.

#### Pregnancy

Clindavasin D cutaneous solution should not be used to treat pregnant women except in cases of proven necessity.

#### Breast-feeding

It is not known whether clindamycin can pass into human breast milk after use as a cutaneous solution. When administered by mouth or injection, clindamycin can be passed into human breast milk and is likely to cause adverse reactions in the infant, such as diarrhea, blood in the stool or rash. Your doctor will consider whether to stop breast-feeding or stop administering the medicine because of the risk of possible side effects to your child.

Clindavasin D should not be applied to the breasts if you are breast-feeding.

### **Driving and using machines**

There is no evidence that Clindavasin D affects the ability to drive and use machines.

## **3. How to use Clindavasin D cutaneous solution**

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

#### Dosage

Clindavasin D cutaneous solution is administered twice a day.

#### Method of application

Remove the cap and insert the automatic dispensing swab applicator provided in the package into the neck of the bottle. Shake well before use.

Wash the affected area of skin, dry it gently and apply a thin film of the solution, gently pressing the pad onto your skin.

After application, close the bottle securely with the extra cap provided in the package.

### **If you use more Clindavasin D cutaneous solution than you should**

If you have applied more than the required amount, please contact your doctor.

### **If you have missed to apply Clindavasin D cutaneous solution**

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

### **If you have stopped the administration of Clindavasin D cutaneous solution**

If you stop treatment, the desired effect will not be achieved or 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.

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 of the lining of the large intestine (pseudomembranous colitis).
- Allergic reaction with rash and itching (especially affecting the whole body).

The following adverse drug reactions are possible with treatment with this medication:

Very common (may affect up to 1 in 10 people)

- Seborrhea (skin disease manifested by impaired secretion of sebum on the skin, scaling of the skin, accompanied by redness and itching);
- Skin irritation;
- Urticaria (hives);
- Dry skin;

Uncommon (may affect 1 to 10 in every 1000 patients)

- Gastrointestinal disorder (may cause symptoms such as diarrhea and nausea).

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

- Hair follicle inflammation (folliculitis);
- Eye burning;
- Eye pain;
- Abdominal pain;
- Pseudomembranous colitis (a serious inflammation of the intestines that may include symptoms such as stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting);
- Skin inflammation caused by contact with irritants or allergens (contact dermatitis).

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:

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

By reporting side effects, you can contribute to getting more information about the safety of this medicine.

## **5. How to store Clindavasin D cutaneous solution**

Keep this medicine out of the sight and reach of children.

Store below 25°C.

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

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 Clindavasin D cutaneous solution contains

- The active substance is clindamycin as clindamycin phosphate. 1 ml of cutaneous solution contains 10 mg of clindamycin.
- Other ingredients are: propylene glycol, isopropyl alcohol, hydrochloric acid, sodium hydroxide, purified water.

#### What Clindavasin D cutaneous solution looks like and contents of the pack

Clindavasin D cutaneous solution is a colourless transparent solution in a white plastic bottle containing 30 ml of solution. Closed and sealed with a white polypropylene screw cap. One bottle with a patient leaflet, together with an additional cap and an automatic dosing swab applicator, packed in a cardboard box.

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#### **Manufacturer**

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

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