

## Package leaflet: Information for the user

### Viralief 50mg/g cream

aciclovir

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### **What is in this leaflet**

1. What Viralief 50 mg/g cream is and what it is used for
2. What you need to know before you use Viralief 50 mg/g cream
3. How to use Viralief 50 mg/g cream
4. Possible side effects
5. How to store Viralief 50 mg/g cream
6. Contents of the pack and other information

#### **1. What Viralief 50 mg/g cream is and what it is used for**

Viralief 50 mg/g cream is a medicine against viral infections (antiviral agents).

#### **Viralief 50 mg/g cream is used for**

- the treatment of cold sores caused by *Herpes simplex* virus.

#### **2. What you need to know before you use Viralief 50 mg/g cream**

##### **DO NOT use Viralief 50 mg/g cream**

- if you are allergic to aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Viralief 50 mg/g cream if you have or in the past have had any medical conditions or illnesses, especially

- severe deficiency of the immune system, e.g.
  - AIDS patients
  - people who have received a bone marrow transplant.

In this case, your doctor may decide to prescribe you tablets instead.

- You should not use Viralief 50 mg/g cream on mucous membranes (e.g. in the mouth, eye or vagina) to avoid local irritation. Accidental eye contact must also be prevented
- If your immune system is seriously weakened talk to your doctor about the treatment of any infection.

#### **Other medicines and Viralief 50 mg/g cream**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The cream should not be mixed with other substances.

#### **Pregnancy and breast-feeding**

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.

The use of Viralief 50 mg/g cream should be considered only when the potential benefits outweigh the possibility of unknown risks. It should be noted that effects of aciclovir cream on the whole body are most likely negligible due to local application to the skin.

#### Breast-feeding

Aciclovir passes into breast milk. Not enough is yet known about the consequences of this. Therefore, contact your doctor or pharmacist if you are breast-feeding.

#### **Driving and using machines**

There is no information available on the effects on the ability to drive or use machines. However, no negative effect is anticipated.

#### **Viralief 50 mg/g cream contains propylene glycol (E1520)**

This medicine contains 150 mg propylene glycol in each gram of cream.

#### **Viralief 50 mg/g cream contains cetyl alcohol**

Cetyl alcohol may cause skin irritation and local skin reactions (e.g. contact dermatitis).

### **3. How to use Viralief 50 mg/g cream**

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

#### **The recommended dose is...**

Viralief 50 mg/g cream should be applied to the infected lips five times a day, at intervals of about 4 hours but not at night.

Viralief 50 mg/g cream should be applied to the lesions or impending lesions as early as possible after the start of an infection.

#### Method of administration

Apply the cream thinly onto the affected skin areas.

#### Duration of treatment

The treatment should be continued for 5 days. If, after 5 days, healing is not complete then treatment can be continued for up to an additional 5 days.

If you have the impression that the effect of Viralief 50 mg/g cream is too strong or too weak, talk to your doctor or pharmacist.

#### **If you use more Viralief 50 mg/g cream than you should**

If you have used more Viralief 50 mg/g cream than recommended or in case of a suspected overdose or misuse you should contact your doctor who will decide upon the measures.

#### **If you forget to use Viralief 50 mg/g cream**

If you have only recently forgotten to apply the cream to your skin, you should still go ahead and apply the cream at the recommended dose. In all other cases, you should wait until the time of your next dose. Do not use a double dose to make up for a forgotten dose.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Transient burning or stinging sensation on the application site, mild form of dry skin or flaking, itching.

#### ***Rare (may affect up to 1 in 1,000 people):***

Skin reactions like erythema, contact dermatitis after administration.

The results of hypersensitivity tests carried out have shown that the reactive substances were mostly components of the cream and not aciclovir itself.

#### ***Very rare (may affect up to 1 in 10,000 people):***

Immediate severe allergic reactions including angioedema (swelling of tongue and/or face) and urticaria (hives).

### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Viralief 50 mg/g cream**

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 package. The expiry date refers to the last day of that 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.

This medicine does not require any special storage conditions.

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

#### **What Viralief 50 mg/g cream contains**

The active substance is aciclovir.

One gram of cream contains 50 mg of aciclovir, equivalent to 5 g of aciclovir per 100 grams of cream.

#### **The other ingredients are:**

Macrogol stearate, dimethicone, cetyl alcohol, liquid paraffin, paraffin, white soft, propylene glycol (E1520), purified water.

#### **What Viralief 50 mg/g cream looks like and contents of the pack**

Viralief 50 mg/g cream is a medicinal product in the form of white to off-white cream. Viralief 50 mg/g cream is supplied in an aluminium tube with a polyethylene cap. The tubes contain 2, 3 or 5 grams of cream.

#### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd , Waterford Road, Clonmel, Co. Tipperary, Ireland

#### **Manufacturer**

Stada Arzneimittel AG, Stadastr. 2-18, D-61118 Bad Vilbel, Germany

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

AT: Aciclostad Fieberblasencreme  
BE: Aciclovir EG Labialis 50 mg/g crème  
DK: Acivir 5%  
FI: Herpolips 50 mg/g - emulsiovoide  
FR: KENDIX 5 POUR CENT, crème  
IE: Viralief 50 mg/g Cream  
LU: Herpolips 50 mg/g crème

**This leaflet was last revised in January 2020.**