

**Package leaflet: Information for the Patient****EFRIVIRALLABIALE 50 MG/G cutaneous stick  
Aciclovir****Equivalent medicine**

**Read all of this leaflet carefully before you start taking 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 to do.
- 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 effects 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 10 days.

**What is in this leaflet:**

1. What EFRIVIRALLABIALE is and what it is for
2. What you need to know before you use EFRIVIRALLABIALE
3. How to take EFRIVIRALLABIALE
4. Possible side effects
5. How to store EFRIVIRALLABIALE
6. Contents of the pack and other information

**1. What EFRIVIRALLABIALE is and what it is used for**

EFRIVIRALLABIALE contains the active substance acyclovir, which is used to treat infections caused by herpes viruses including the *herpes simplex* virus.

EFRIVIRALLABIALE is indicated for the treatment of herpes simplex viral infections of the lips (frequent herpes labialis) in adults and adolescents over 12 years of age.

Talk to your doctor if you do not feel better or if you feel worse after 10 days.

**2. What you need to know before you take EFRIVIRALLABIALE****DO NOT use EFRIVIRALLABIALE**

- If you are allergic to aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in section 6).
- In children under 12 years of age (see "Children" in section 3).

**Warnings and Precautions****Talk to your doctor before using EFRIVIRALLABIALE**

- If you doubt that your lesion is labial herpes.
- If you have a particularly severe form of cold sores.
- If your immune system is compromised (for example if you have undergone a bone marrow transplantation or if you have AIDS). In this case, consult your doctor for treatment of any infections.

**Be careful with EFRIVIRALLABIALE**

EFRIVIRALLABIALE is for external use only and should only be used to treat lesions on the lips caused by herpes simplex. It is not recommended to apply it on mucous membranes, such as those of the mouth (for example in the case of mouth ulcers), nose, eyes and it should not be used for the treatment of genital herpes.

Do not scratch the lesions unnecessarily and do not touch them with a towel to avoid worsening or transmitting the infection. Always wash your hands before and after applying the cutaneous stick or after touching the lesions. In particular, do not touch your eyes after touching the lesions or applying the cutaneous stick.

Particular care should be taken to avoid accidental application into the eyes. If the contents of the cutaneous stick accidentally come into contact with your eyes, carefully wash them with warm water.

If you have any doubts, consult your doctor.

Prolonged use of the product can lead to sensitization phenomena (allergic reactions). If this happens, stop the treatment and consult your doctor.

It is recommended that people with particularly severe forms of recurrent cold sores consult their doctor. Be careful and consult your doctor if you are unsure if you have cold sores.

It is recommended that those with cold sores avoid transmission of the virus especially when active lesions are present.

**Other medicines and EFRIVIRALLABIALE**

Tell your doctor or pharmacist if you are using, have recently used or could use any other medicines, even those obtained without a prescription. EFRIVIRALLABIAL is unlikely to interact significantly with other medicines.

**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 using this medicine.

During pregnancy and / or breast-feeding, EFRIVIRALLABIALE should be used only after consulting the doctor who will assess the potential risks and benefits for the mother and the baby.

**Driving and using machines**

Negative effects on the ability to drive vehicles or using machines are not known.

**Important information about some of the ingredients of EFRIVIRALLABIALE**

EFRIVIRALLABIALE contains butylated hydroxytoluene. It can cause localized skin reactions (e.g. contact dermatitis) or irritation at eyes and mucous membranes.

**3. How to take EFRIVIRALLABIALE**

Always use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist. If you have any doubts, consult your doctor or pharmacist.

EFRIVIRALLABIALE is for external use only.

It is important to start treatment as soon as the first symptoms of the infection appear (for example itching and / or burning and / or pain).

In the event that treatment has not been started at the onset of the first symptoms of the infection, it can also be started when the vesicles appear. EFRIVIRALLABIAL is however effective both used in the initial phase of infection (itching and/or burning and/or pain), and in the vesicular phase.

Wash your hands before and after applying the cutaneous stick and avoid unnecessarily scratching the lesions or touching them with a towel in order to avoid worsening or transmitting the infection.

### **How much**

Warning: do not exceed the recommended dose.

#### *Adults and adolescents over 12 years of age*

Apply directly from the container the amount of medicine necessary to cover the entire infected area, including the external limit of the vesicles, 5 times a day at intervals of about 4 hours throughout the day, avoiding the nocturnal application.

#### *Children under the age of 12*

EFRIVIRALLABIALE should not be used in children under the age of 12 (see section DO NOT use EFRIVIRALLABIALE).

### **How long**

Treatment must continue for at least 4 days. If there is no healing, treatment can continue for up to 10 days. If the lesions are still present after 10 days, consult your doctor. Do not exceed the recommended dose.

The maximum effectiveness of EFRIVIRALLABIALE is obtained when it is used promptly, at the beginning of a herpetic lesion. For best results, the medicine should be applied at the first signs of herpes (tingling, redness, swelling or itching) or at the first appearance of lesions (vesicles).

Consult your doctor if the disorder occurs repeatedly or if you notice any recent changes in its characteristics.

### **How**

The medicine should be applied directly to the lesions without using hand contact; however, patients must wash their hands after application; it is needed to avoid unnecessarily rubbing the lesions or touching them with a towel in order to avoid worsening or transmitting the infection.

**The medicinal product is for personal use only. Once it is opened, it must be used by the same patient only, for as long as it lasts, and never shared with other individuals..**

### **If you use more EFRIVIRALLABIAL than you should**

If you use more than you should, you should seek advice with your doctor or pharmacist immediately, taking this package with you.

EFRIVIRALLABIALE is a preparation for topical use.

Even if the content of the pencil is accidentally applied in excess or ingested, no undesirable effects are expected. In case of accidental ingestion/intake of EFRIVIRALLABIALE, notify your doctor immediately or go to the nearest hospital, taking the package with you to show.

**If you forget to use EFRIVIRALLABIALE**

If you forget to use the medicine, apply it as soon as possible and then continue the use it as usual. Do not apply double the amount to make up for forgotten doses.

**If you have any further doubts on the use of EFRIVIRALLABIALE, ask your doctor or pharmacist.**

**4. Possible side effects**

Like all medicines, EFRIVIRALLABIALE can cause side effects, although not everybody gets them. The following side effects have been reported for the topical use of aciclovir:

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

- temporary pain or burning feeling after EFRIVIRALLABIALE is applied
- moderate skin dryness and flaking
- itching

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

- erythema (redness of the skin)
- contact dermatitis after application. Where sensitivity tests were conducted, results showed that the substances that caused reactions were the stick components rather than aciclovir.

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

- immediate allergic (hypersensitivity) reactions including angioedema (swelling of the lips, of the face, neck and throat) and hives (skin reaction).

In the event of an allergic reaction with symptoms such as facial swelling, stop using the product and contact your doctor immediately.

These side effects are usually transient.

Follow the instructions contained in this information leaflet minimise the risk of undesirable effects.

**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 the national reporting system at: <http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store EFRIVIRALLABIALE**

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

Do not use this medicinal product after the expiration date shown on the label. The expiry date refers to the last day of that month.

The expiry date refers to the unopened and correctly stored package.

Store in the original package to protect from light. Do not store above 25°C.

Do not refrigerate.

After the first opening of container, the product must be used within the expiration date shown on the package; after that time, what remains of the product has to be disposed of.

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.

**Important: keep the medicinal product information- box or information leaflet- at hand.**

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

EFRIVIRALLABIAL contains aciclovir, an antiviral agent active against the herpes labialis virus.

One gram contains

Active ingredient: Aciclovir 50 mg

Excipients: Castor oil, semi-synthetic glycerides, carnauba wax, white paraffin, beeswax, octyldodecanol, **butylated hydroxytoluene**, vanilla flavour.

### **Description of the appearance of EFRIVIRALLABIALE**

EFRIVIRALLABIALE is presented in form of cutaneous stick, included in a cylindrical container/applicator which delivers the medicine, by rotating the top. A box contains 1 applicator and a 3 g stick.

### MARKETING AUTHORISATION HOLDER AND MANUFACTURER

#### **Marketing Authorisation Holder**

AESCULAPIUS FARMACEUTICI S.r.l.

Via Cefalonia, 70 – 25124 BRESCIA

#### **Manufacturer**

Laboratorio Chimico Farmaceutico A. Sella srl - Via Vicenza, 67 - Schio (VI)

**This leaflet was last revised in: February 2020**