

**Information leaflet: Information for the patient****Efrivirallabiale 50 mg/g cream**

Aciclovir

Generic drug

**Read this leaflet carefully before using this medicinal product because it contains important information for you.**

- Use always this medicinal product as exactly described in this leaflet or as your doctor or the pharmacist told you to do.
- Keep this leaflet. You might need reading it again.
- Consult your pharmacist if you need more information or advice.
- If any undesirable effect is evident, including those not listed in this leaflet, please ask your doctor or pharmacist. See section 4.
- Consult your doctor if you do not notice any improvement or if you notice that symptoms worsen after 10 days.

**Content of this leaflet:**

1. What EFRIVIRALLABIALE is and what it is used for
2. What you must know before using EFRIVIRALLABIALE
3. How to use EFRIVIRALLABIALE
4. Possible undesirable effects
5. How to keep EFRIVIRALLABIALE
6. Content of the package and other information

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

The active ingredient of EFRIVIRALLABIALE is aciclovir. Aciclovir is used to treat infections caused by herpes viruses (*herpes*), including *herpes simplex*.

EFRIVIRALLABIALE is indicated for the treatment of *herpes simplex* virus infections of the lips (recurrent *herpes labialis*) in adults and adolescents (12 years or older).

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

**2. What you must know before using EFRIVIRALLABIALE****Do not use EFRIVIRALLABIALE**

- If you are allergic to aciclovir, valaciclovir or any of the other components of this medicinal product (listed in section 6);

- For children under 12 years of age (see 'Children' in section 3).

### **Warnings and precautions for use**

#### **Consult your doctor or pharmacist before using EFRIVIRALLABIALE**

- If you are not sure of having *herpes labialis*.
- If you suffer from a particularly severe case of *herpes labialis*.
- If your immune system is compromised (e.g. if you have undergone a bone-marrow transplant or if you have AIDS). Should this be the case, consult your doctor to treat any other kind of infection.

#### **Pay attention with EFRIVIRALLABIALE**

EFRIVIRALLABIALE is for external use only and it should only be used to treat lesions on the lips caused by *herpes simplex*. It is not recommended to be applied on mucous membranes such as those in the mouth (e.g. in case of mouth ulceration), eyes and nose. Do not use this product to treat *herpes genitalis*.

Do not rub on the lesions unnecessarily and do not touch them with a towel to avoid worsening or transmitting the infection. Wash your hands before and after applying the cream or after touching the lesions. In particular, do not touch your eyes after touching the lesions or applying the cream.

Take special care not to accidentally apply this product on your eyes. If the cream accidentally comes into contact with your eyes, wash them thoroughly with warm water.

If you are in any doubt, consult your doctor.

This product may cause sensitisation, especially when used for a prolonged period (allergic reactions). Should this occur, discontinue the treatment and consult your GP.

Consult your doctor if you suffer from particularly severe cases of *herpes labialis*. Pay attention and consult a doctor if you are not sure of having *herpes labialis*.

#### **Interactions of EFRIVIRALLABIALE with other medicinal products**

Tell your doctor or pharmacist if you are using, have recently used or could use any other medicinal product, including those drugs that can be bought without a medical prescription. The use of EFRIVIRALLABIALE is unlikely to interact significantly with other medicinal products.

#### **Pregnancy, lactation and fertility**

If you are or if you suspect you are pregnant or you are planning pregnancy, or if you are breastfeeding, ask your doctor or pharmacist for advice before taking any drug.

If you are pregnant and/or breastfeeding, EFRIVIRALLABIALE should be administered only after you consult a doctor who will assess the potential risks and benefits for mother and baby.

#### **Effects on ability to drive and use machines**

It has no negative effects on the ability to drive and use machines.

#### **Relevant information on some EFRIVIRALLABIALE excipients**

EFRIVIRALLABIALE contains propylene glycol. It can cause skin irritation.

EFRIVIRALLABIALE contains cetostearyl alcohol. It can cause localised skin reactions (e.g. contact dermatitis).

### 3. How to use EFRIVIRALLABIALE

Use this medicinal product always following the indications in this leaflet or the instructions given by your doctor or pharmacist. If in doubt, consult your doctor or pharmacist.

EFRIVIRALLABIALE is for external use only.

Initiate treatment as soon as the first symptoms of the infection arise (e.g. itching and/or burning sensation and/or pain).

If treatment is not started at the onset of the first symptoms of the infection, it can be also started when blisters appear. In any case, EFRIVIRALLABIALE is effective if used both in the initial stage of infection (itching and/or burning sensation and/or pain), and in the blistering phase.

Wash your hands before and after applying the cream. Avoid scratching the lesions or touching them unnecessarily using a towel as this may worsen the sore or transmit the infection.

#### How much

Caution: do not exceed recommended dosage.

#### *Adults and adolescents (12 years or older)*

Apply the amount of cream needed to cover the entire infected area, as well as the outer edges of any blisters, 5 times a day, about every 4 hours per day. Do not use at night.

#### *Children under 12 years of age*

EFRIVIRALLABIALE should not be used in infants and children under 12 years old (see the 'Do NOT use EFRIVIRALLABIALE' section).

#### For how long

Treatment should last at least 4 days. If lesions are not healed, treatment may continue up to 10 days. If lesions are still present after 10 days, consult a doctor. Do not exceed recommended dosage.

Initiate treatment as soon as the first symptoms of the infection arise (e.g. itching, and/or burning sensation and/or pain) or right after lesions (blisters) appear.

Consult your doctor if this disorder is recurrent or if you notice any changes in the symptoms.

#### Method of administration

Take a small quantity of the cream and apply it onto the infected area, covering the lesion.

Wash your hands before and after applying the cream.

Avoid scratching the lesions or touching them unnecessarily using a towel as this may worsen the sore or transmit the infection.

#### If you use more EFRIVIRALLABIALE than recommended

If you have used more than the recommended dose, talk to your doctor or pharmacist immediately, and show him the package.

EFRIVIRALLABIALE is a preparation for topical use.

Even if the cream is accidentally applied in excess or ingested, no undesirable effects are expected. In case you accidentally swallow EFRIVIRALLABIALE, seek immediate medical advice- call and inform your doctor or go to the nearest hospital. Taking the package with you.

**If you forget using EFRIVIRALLABIALE**

Do not worry if you forget using the cream. Apply the cream as soon as you remember, and continue the treatment as before. Do not apply a double amount of cream to compensate for the forgotten doses.

**If you are in any doubt on how to use EFRIVIRALLABIALE, you should consult your doctor or pharmacist.**

**4. Possible undesirable effects**

Like all medicines, EFRIVIRALLABIALE can have side effects, although not everybody gets them. Undesirable effects reported for aciclovir cream are:

**Uncommon undesirable effects (may affect fewer than 1 over 100 individuals):**

- Temporary pain or burning feeling after application
- Moderate skin dryness or flaking
- Itching

**Rare undesirable effects (may affect fewer than 1 over 1,000 individuals):**

- Erythema (skin redness)
- Contact dermatitis after application. Where sensitivity tests were conducted, results showed that the substances that caused reactions were the base components of the cream rather than aciclovir.

**Very rare undesirable effects (may affect fewer than 1 over 10,000 individuals):**

- Immediate allergic reactions (hypersensitivity), including angioedema (lips, face, neck and throat swelling) and urticaria (skin reaction).

If an allergic reaction occurs, with symptoms such as swelling of the face, stop using the product and contact your doctor immediately.

These undesirable effects are often temporary.

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

**Reporting of suspected adverse effects**

If any undesirable effect is evident, including those not listed in this leaflet, please ask your doctor or pharmacist. You can also report undesirable effects directly in the reporting Italian national system in the address: <http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>. Reporting undesired effects is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

**5. How to keep EFRIVIRALLABIALE**

Keep this medicinal product out of sight and reach of children.

The sealing membrane of the tube opening must be intact.

Do not use the medicinal product after the expiry date specified on the package. The expiry date refers to the last day of that month.

The expiry date applies if the product is properly stored and its package is not damaged.

Do not store above 25°C. Do not refrigerate.

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. Content of the package and other information

EFRIVIRALLABIALE contains aciclovir, an antiviral which is active against *herpes labialis* virus.

One gram of product contains:

**Active ingredient:** Aciclovir 50 mg

**Excipients:** Cetostearyl alcohol, liquid paraffin, poloxamer 407, sodium lauryl sulphate, purified water, white petrolatum, arlancel 165, dimethicone 20, propylene glycol.

### Description of EFRIVIRALLABIALE appearance and content of the package

EFRIVIRALLABIALE is available in the form of cream for cutaneous use, in a 3 g aluminium tube.

One tube contains 150 mg of aciclovir (5%).

### Marketing authorisation holder and Manufacturer

Marketing authorisation holder

AESCULAPIUS FARMACEUTICI S.r.l.

Via Cefalonia 70 - 25124 - BRESCIA

Manufacturer

Special Product's Line S.p.A.

Via Fratta Rotonda Vado Largo, 1 – 03012 Anagni (FR)

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