

## Package Leaflet: information for the user

### Acic Cold Sore 5% w/w 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 as your doctor, pharmacist or nurse 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 of the side effects, talk to your doctor, pharmacist or nurse. 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 Acic is and what it is used for
2. What you need to know before you use Acic
3. How to use Acic
4. Possible side effects
5. How to store Acic
6. Contents of the pack and other information

**ROWEX**<sup>®</sup>

### 1 What Acic is and what it is used for

The name of your medicine is Acic. This belongs to a group of medicines that treat viral infections.

Acic is used to treat cold sores. These are caused by the herpes simplex virus.

### 2 What you need to know before you use Acic

#### Do not use Acic:

- if you are allergic to aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in Section 6).
- on sores inside your mouth, on the eyes or on your genitals.

Do not use Acic if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Acic.

#### Warnings and precautions

Talk to your doctor or pharmacist before using Acic if you have any problems which might weaken your immune system or if you have severe cold sores.

#### Children and adolescents

As for adults

#### Other medicines and Acic

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

- Acic should not affect any other medicines you are taking by mouth.

#### 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 any medicine.

#### Driving and using machines

This medicine is unlikely to affect you being able to drive or use any tools or machines. However, you should wait to see how Acic affects you before you try these activities.

#### Acic contains:

- Cetyl alcohol: May cause skin reactions where you apply the cream such as dermatitis.
- 300 mg of propylene glycol in each 2 g tube which is equivalent to 150 mg/g of cream.

### 3 How to use Acic

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.

#### Adults and children:

- Start using the cream when you get the first signs of infection. You may see skin blisters or be able to recognise the tingle sensation that means that a blister will appear soon.
- Spread a thin layer of cream onto the cold sore about every 4 hours during your day. This is usually about 5 times each day.
- It is best to use a cotton bud to apply the cream. If you do use your fingers instead, wash them thoroughly before and after using the cream. This is to prevent you spreading the virus to your damaged skin or to new areas.
- Use the cream for at least 4 days. If your cold sore has not healed completely after 4 days, carry on using the cream for 6 more days. **If the cold sore has not healed after a total of 10 days, stop using the cream and tell your doctor.**
- If you feel your cold sore is getting worse tell your doctor.
- Do not get the cream in your eyes.

- Do not use the cream inside your mouth or vagina. It may irritate your skin in these areas.

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

Please talk to your doctor or pharmacist if you have used more Acic than you should.

#### **If you swallow Acic**

It is probably not harmful if the cream is swallowed.

However, please tell your doctor or pharmacist if you feel worried or if you get any side effects after swallowing the cream.

#### **If you forget to use Acic**

- continue using it as soon as you remember.
- Do not use more cream to make up for the time you forgot.

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.

**Allergic reactions** (affects less than 1 in 10,000 people)

If you have an allergic reaction, **stop using this medicine and see a doctor straight away.**

The signs may include:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or having trouble breathing
- unexplained fever and feeling faint especially when standing up

#### **Other side effects**

**Uncommon:** may affect up to 1 in 100 people

- a burning or stinging feeling after you apply the cream that goes away
- mild drying or flaking of your skin
- itching

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

- redness of your skin
- skin rash

#### **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 HPRC 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 Acic**

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 tube and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package.

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

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 Acic contains**

- The active substance is aciclovir. Each gram (g) of the cream contains 50 milligrams (mg) of aciclovir [5% w/w].
- The other ingredients are propylene glycol, white soft paraffin, liquid paraffin, cetyl alcohol, dimeticone 350, stearyl macrogolglycerides and purified water.

#### **What Acic looks like and contents of the packs**

- Acic is a white to off-white cream mass
- It is supplied in a 2g tube.

#### **Marketing Authorisation Holder:**

Rowex Ltd., Bantry, Co. Cork, Ireland

#### **Manufacturers:**

Salutas Pharma GmbH, Betriebsstätte Osterweddingen, Lange Göhren 3, 39171 Osterweddingen, Germany  
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

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