

PACKAGE LEAFLET: INFORMATION FOR THE USER

Acerbine solution

DL-malic acid, salicylic acid, benzoic acid

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

1. What *Acerbine solution* is and what it is used for

This medicine is a solution for topical application.

How *Acerbine solution* works

Acerbine solution is a disinfectant, relieves pain, and accelerates wound healing. It promotes the detachment of dead tissues from the surface of the wound, and at the same time promotes the formation of new, healthy tissue. Because of its special composition, *Acerbine solution* has an antiseptic effect; it ensures the proper fluid balance in the wound area and helps the healing process in many ways.

Uses

Acerbine solution is suitable for the treatment of superficial skin injuries, such as burns, scalds, sunburn, wounds and abrasions.

2. What you need to know before you use *Acerbine solution*

Do not use *Acerbine solution*

- if you are allergic (hypersensitive) to malic acid, salicylic acid, benzoic acid, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using *Acerbine solution*.

- if you have extensive wounds and burns, consult your doctor.

- if you have an ulcer, a bedsore (pressure sore from staying in bed) or are being prepared for a skin graft, you must consult a doctor.
- if you have impaired kidney function, you should not use *Acerbine solution* on large areas and for long periods.

Acerbine solution must not come into contact with the mucous membranes, in particular around the eyes and mouth; wash your hands after use.

If the symptoms persist, if you have unexplained symptoms or if the solution does not produce the expected effect, you should consult your doctor.

Children

Acerbine solution is not recommended for use in newborns.

Other medicines and *Acerbine solution*

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

No interactions have been reported to date.

Salicylic acid can, however, accelerate the uptake of other medicinal products applied to the same area.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you are pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking or using any medicine.

In principle, the use of *Acerbine solution* is possible during pregnancy and breast feeding.

During pregnancy and breast feeding *Acerbine solution* should only be used on small areas.

During breast feeding, *Acerbine solution* should not be applied in the area of the breast.

Driving and using machines

Acerbine solution has no or negligible influence on the ability to drive and use machines.

***Acerbine solution* contains**

Individual ingredients (benzoic acid, salicylic acid, propylene glycol) which can cause skin irritation. *Acerbine solution* is well tolerated when used in accordance with the instructions.

3. How to use *Acerbine solution*

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.

Spray *Acerbine solution* on the wound or cover with a sterile dressing soaked in *Acerbine solution*.

The recommended dosage is:

Infants, children and adults:

Apply *Acerbine solution* to the wound or damaged skin two or more times daily, or moisten the dressing repeatedly with it. Once scar formation begins, one application per day is generally sufficient.

The period of use depends on how quickly your wound is healing.

If this is taking a long time, you should see a doctor to check the treatment.

If you use more *Acerbine solution* than you should

No cases of *Acerbine solution* overdoses have been reported.

If too much *Acerbine solution* is used on large areas over a long period, mild signs of intoxication can occur, particularly in children, due to the uptake of salicylic acid in the body. The signs are nausea, vomiting, dizziness, headache, tinnitus, sweating and confusion. These symptoms are avoided by reducing the dose.

Salicylic acid at high doses can cause minor bleeding and prolong the bleeding time.

If you forget to use *Acerbine solution*

Continue to apply the usual quantity of the product, without increasing the dose.

If you stop using *Acerbine solution*

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, *Acerbine solution* can cause side effects, although not everybody gets them.

Such side effects can occur with the following incidence rates:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100, <1/10$)
- Uncommon ($\geq 1/1,000, <1/100$)
- Rare ($\geq 1/10,000, <1/1,000$)
- Very rare ($<1/10,000$)

Unknown (incidence rate cannot be determined based on available data).

Immune system disorders

Very rare A previously unknown allergic hypersensitivity reaction (contact sensitisation) to salicylic acid can occur.

General disorders and complaints at the administration site

Uncommon After applying *Acerbine solution* a temporary sensation of heat or pain can often be experienced, after which the patient notices rapid and lasting pain relief.

Rare In rare cases, slight reddening of the skin and a rash can develop on the healthy tissue immediately surrounding the treated wound area.

Reporting 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 may also report side effects by using the national reporting system:

Austrian Federal Office for Safety in Health Care
Traisengasse 5
AT-1200 VIENNA
Fax: +43 (0) 50 555 36207
Internet: <http://www.basg.gv.at>

By reporting side effects, you can contribute to making more information on the safety of this medicine available.

5. How to store *Acerbine solution*

Do not store above 30°C.
Keep the bottle in the outer carton, in order to protect it from light.

After opening, do not use for more than 12 months.

Keep out of the reach and sight of children.

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

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the package and other information

What *Acerbine solution* contains

- The active substances are: DL-malic acid, benzoic acid and salicylic acid.
1 g contains 21.5 mg DL-malic acid, 1.5 mg benzoic acid and 0.4 mg salicylic acid.
- The other ingredients are propylene glycol and purified water.

What *Acerbine solution* looks like and contents of the pack

Clear, yellowish solution in 30 ml and 80 ml spray bottles in a carton.

Marketing Authorisation Holder and Manufacturer

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

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