

PACKAGE LEAFLET: INFORMATION FOR THE USER

Acerbine-ointment

Active substances: DL-malic acid, benzoic acid, salicylic 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 ointment* is and what it is used for
2. What you need to know before you use *Acerbine ointment*
3. How to use *Acerbine ointment*
4. Possible side effects
5. How to store *Acerbine ointment*
6. Contents of the pack and other information

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

Ointment for the treatment of superficial skin injuries such as burns, scalds, sunburn, wounds and abrasions.

How *Acerbine ointment* works

Acerbine ointment is a disinfectant, relieves pain, and accelerates wound healing. It favours 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 this product has an antiseptic effect; it ensures the correct fluid balance and helps the healing process in many ways.

Acerbine ointment is easy to spread. The ointment base has a low fat content and is suitable particularly for the treatment of weeping wounds, uncovered areas of the body (e.g. the face), and hairy parts of the body.

You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

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

Do not use *Acerbine ointment*

- if you are allergic (hypersensitive) to malic acid, benzoic acid, salicylic 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 ointment*

- 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 transplant you must consult a doctor.
- if you have impaired kidney function, you should not use *Acerbine ointment* over a large area and for long periods.

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

When used correctly *Acerbine ointment* is well tolerated; individual ingredients can cause skin irritation (benzoic acid, propylene glycol).

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

Children

Acerbine ointment is not recommended for use in new-born babies.

Other medicines and *Acerbine ointment*

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, increase the uptake of other medicinal products applied in the same area.

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 *Acerbine ointment* is possible in principle during pregnancy and breast feeding.

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

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

Driving and using machines

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

3. How to use *Acerbine ointment*

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:

Infants, children and adults:

Apply *Acerbine ointment* to the wound or damaged skin several times daily.

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

If you use more *Acerbine ointment* than you should

No cases of overdosage have been reported with *Acerbine ointment*.

If too much *Acerbine ointment* is used on large areas over a long period, mild signs of intoxication can occur, particularly in children, due to uptake of salicylic acid in the body. The signs are nausea, vomiting, dizziness, headache, buzzing in the ears, 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 ointment*

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

If you stop using *Acerbine ointment*

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

4. Possible side effects

The following frequency statements are used for the evaluation of undesirable effects:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$ to $< 1/10$)
- Uncommon ($\geq 1/1,000$ to $< 1/100$)
- Rare ($\geq 1/10,000$ to $< 1/1,000$)
- Very rare ($< 1/10,000$)
- Not known (cannot be estimated from the available data).

The following adverse reactions may occur:

Immune system disorders

Very rare: A hitherto unknown allergic hypersensitivity reaction (contact sensitisation) to salicylic acid may occur.

General disorders and administration site conditions

Common: Upon application, *Acerbine ointment* may lead to a transient sensation of warmth, after which the patient experiences rapid, lasting pain relief.

Rare: Mild erythema and urticarial rash may occur on healthy tissue immediately around the treated wound area.

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:

Bundesamt für Sicherheit im Gesundheitswesen

(Federal Office for Safety in Health Care)

Traisengasse 5

1200 VIENNA

AUSTRIA

fax: + 43 (0)50 555 36207

website: <http://www.basg.gv.at/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Acerbine ointment*

Keep the tube in the outer carton in order to protect from light.

After opening, do not use for more than 6 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 pack and other information

What *Acerbine ointment* contains

- The active substances are: DL-malic acid, salicylic acid, benzoic acid.
1 g contains 7 mg DL-malic acid, 0.5 mg benzoic acid and 0.133 mg salicylic acid.
The other ingredients are propylene glycol, xalifine and purified water.

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

Colourless ointment in 30 g and 100 g tubes in a carton.

Marketing Authorisation Holder and Manufacturer

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Marketing Authorisation Number: 16.169

This leaflet was last approved in 03.2014.