

PACKAGE LEAFLET: INFORMATION FOR THE USER

ACETOCAUSTIN

0,5 ml, Cutaneous solution

MONOCHLOROACETIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What ACETOCAUSTIN is and what it is used for
2. Before you take ACETOCAUSTIN
3. How to take ACETOCAUSTIN
4. Possible side effects
5. How to store ACETOCAUSTIN
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1. WHAT ACETOCAUSTIN IS AND WHAT IS IT USED FOR

ACETOCAUSTIN is a preparation for the removal of warts.
ACETOCAUSTIN is used to cauterize (remove) common warts (verrucae vulgaris).

2. BEFORE YOU TAKE ACETOCAUSTIN

You need a viscous, well adhering ointment or paste (eg Vaseline or zinc paste) to protect the healthy skin around the warts.

Warning

Healthy skin that has accidentally come into contact with ACETOCAUSTIN should be thoroughly rinsed with running water.

Do not use ACETOCAUSTIN

- If you are hypersensitive (allergic) to monochloroacetic acid
- in the area of the face (ACETOCAUSTIN shall never come into contact with the eyes or mucous membranes of the nose and mouth)
- in the genital area

- on wounds or injured warts
- immediately after surgical removal of warts using a scalpel or electric knife, after freezing the wart (cryotherapy), subcutaneous injection of bleomycin, as well as laser treatment (applies in particular to cases where the skin is red or inflamed from the treatment. In this case you should wait at least 4 weeks until redness or inflammation of the skin are fully healed. Only then you can begin treatment with ACETOCAUSTIN).
- for the treatment of moles and warts in elderly
- when you have a tendency to form scar tissue (keloids)

Take special care with ACETOCAUSTIN

- If there is any doubt about the diagnosis (for example, changes in the skin that are not clearly recognizable as warts)

- in the case of impaired immunity (for example, when taking cytostatic)

In these cases ACETOCAUSTIN should not be used without medical supervision.

- for patients with diabetes mellitus, polyneuropathy, arterial occlusion disease and other diseases accompanied by reduced blood flow and / or a limited sensitivity.

In these cases ACETOCAUSTIN should not be used without medical supervision. The solution ACETOCAUSTIN should be applied by a doctor or properly trained personnel.

Special precautionary measures for children

ACETOCAUSTIN contains highly corrosive active substance monochloroacetic acid. Because of its toxic (poisonous) properties, in case that the child completely swallows it, the consequences can be fatal, especially in young children who weight under 15 kilograms. Users are advised to keep the product out of the sight and reach of children, especially young children.

Prevent children from coming into contact with ACETOCAUSTIN during and after its use.

ACETOCAUSTIN should not be used

during pregnancy

in women, in whom pregnancy cannot be excluded with certainty

during breastfeeding

Use in children

Only a doctor can apply ACETOCAUSTIN in children younger than 6 years. In older children the solution must be applied by adults.

Important warnings about the active substance of ACETOCAUSTIN

Be careful when using the solution for application on the warts.

The solution ACETOCAUSTIN is extremely irritating!

Healthy skin around the warts should be covered before the treatment with well adherent, viscous ointment (such as Vaseline or zinc paste), in order to protect the skin from corrosive effects of ACETOCAUSTIN (see section 3: How to use ACETOCAUSTIN?).

It is important to avoid skin contact with the screw cap. Always keep the bottle in an upright position.

If the contents of the bottle are accidentally spilled, make sure that the corrosive solution is immediately removed. During cleaning ensure adequate protection for yourself (for example, washing clothes that accidentally came into contact with ACETOCAUSTIN). Immediately dispose of the absorbing material.

After use, a bottle of ACETOCAUSTIN should be sealed with safety cap. It is important to check that the bottle is securely closed. If the safety cap no longer works, you should immediately return the bottle to the pharmacy or toxic waste landfill for further processing.

Taking other medicines

To date, there are no known interactions with other medicines.

3. HOW TO TAKE ACETOCAUSTIN

If the doctor has not prescribed otherwise, apply a small amount of ACETOCAUSTIN once a week on the wart with a spatula. ACETOCAUSTIN should not be used more than once a week.

Tips for opening the bottle

The bottle is designed to ensure stability during the application! The solution is in a plastic container inside a bottle. For safety reasons, the container is filled with only a small amount of solution. Never attempt to remove the plastic container from the bottle. Never use a tool (for example, a knife, scissors, screwdriver, etc.) to open the bottle of ACETOCAUSTIN!

On one side of the box there is a perforated circle. Press this perforation and put the bottle of ACETOCAUSTIN in the formed opening in the box. During opening and application, the bottle should be constantly standing in a box so it should not fall.

ACETOCAUSTIN is secured with safety cap for children.

The bottle is opened by pressing and turning the shutter. The solution must not come into contact with clothing or textiles.

The solution ACETOCAUSTIN is strongly corrosive and active even in very small quantities. Only a small amount of the solution, which does not have to even be visible to the naked eye, adheres to the blade. If you have any doubt, dip the spatula in the solution and drag it over a piece of paper. You should see a thin line on the paper. The paper should be disposed of immediately afterwards.

Preparation

Since monochloroacetic acid is quickly absorbed by the skin and it reaches deeper skin layers, healthy skin around the warts should be covered before the treatment with well adherent, viscous ointment (such as Vaseline or zinc paste), in order to protect the skin from corrosive effects of ACETOCAUSTIN.

It is the only way to prevent the spread of acid on the skin and to prevent related tissue damage. Since swelling of the surrounding tissue cannot be excluded after applying ACETOCAUSTIN (see section "What are possible side effects?"), tight fitting jewelry (for example, a finger ring) should be removed before application.

Application:

Protect healthy skin with Vaseline!

Place a box with a bottle of ACETOCAUSTIN, which is located within the perforated opening on a stable and solid surface. Keep it out of sight and reach of children. After opening, dip the spatula in the solution. Then apply the solution to the skin. As ACETOCAUSTIN has strong corrosive effect, the amount of one spatula per week is sufficient to achieve the desired result. Never apply more than one spatula!

Use in children

Only a doctor can apply ACETOCAUSTIN in children younger than 6 years. In older children the solution must be applied by adults.

Never use ACETOCAUSTIN more than once a week.

If there is more than one wart in the treated area, treat only one wart and wait for response before treating other warts. The cells destroyed by corrosive effects of ACETOCAUSTIN eventually take on whitish color and the body rejects them. Do not remove the dead tissue mechanically before another application, because even minor injury to the skin can cause inflammation. Strong corrosive effect of ACETOCAUSTIN can cause scarring. When applying the solution to hardly accessible areas of the body (eg, foot), particularly in patients with limited mobility, the assistance of another person is required. The same applies to cases with impaired fine motor function (hand tremors, stiffness in the finger joints).

After application:

Close the bottle of ACETOCAUSTIN, make sure it is firmly closed and that the safety cap functions. Allow the solution to dry for about 5 minutes and then remove ointment or paste around the warts. Always keep bottle of ACETOCAUSTIN in upright position, tightly closed and out of the sight and reach of children.

The average duration of application is 5 weeks. Please consult your doctor or pharmacist if you feel that the effect of ACETOCAUSTIN is too strong or too weak.

Overdose and other errors in the application

Special warning:

Healthy skin that accidentally comes into contact with a solution ACETOCAUSTIN should be rinsed immediately with plenty of water. This is also necessary if during the first few minutes there are no symptoms, because ACETOCAUSTIN can cause serious chemical burns and burns (up to third degree). Immediately consult a doctor if skin irritation occurs despite thorough rinsing. The doctor will treat the affected parts as burns using standard treatments.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ACETOCAUSTIN** can cause side effects, although not everybody gets them. Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Common:

- Irritation of the skin such as burning, pain, redness of the skin. This is especially observed when ACETOCAUSTIN is used immediately after the removal of warts with a scalpel or after cryosurgery, after subcutaneous injection of bleomycin or with injured warts after laser treatment.
- Pain, burning and redness of the skin in the wart area. This is especially observed precautions and warnings are not respected (see section 2. What you need to know before you use ACETOCAUSTIN?).

Very rare:

- Increased scarring
- hypersensitivity reactions
- burns, 3rd degree
- bacterial infections

In individual cases there may be hypersensitivity reactions such as redness, a swelling, blistering and pain, which may affect area significantly greater than the one treated.

The treatment should be discontinued in case of formation of bubbles, tissue necrosis or significant inflammatory response. In isolated cases limfangitis was reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ACETOCAUSTIN

Keep out of the reach and sight of children.

Keep the bottle well closed in upright position.

Do not use **ACETOCAUSTIN** after the expiry date which is stated on the label.

6. FURTHER INFORMATION

What ACETOCAUSTIN contains

The active substance is monochloroacetic acid.

100 mg of solution contains 50 mg of monochloroacetic acid.
ACETOCAUSTIN is available in pack with 0.5 ml solution for administration to the skin.
The bottle with 0.5 ml of a solution contains 297.5 mg of monochloroacetic acid.
The other component is purified water.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

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