Package leaflet: Information for the user

Alacare 8 mg medicated plaster

5-aminolevulinic acid

Read all of this leaflet carefully before you start using 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alacare is and is and what it is used for

Alacare is used for the treatment of mild skin abnormalities on the head or face called solar keratosis. These are small, rough, spots which develop on the skin. They are caused by a lot of exposure to the sun over many years. They are also called actinic keratosis.

Treatment with Alacare is a two-step procedure and is called ‚photodynamic therapy'. It consists of Alacare plaster application to the spots for 4 hours. This is followed by illumination with red light for a couple of minutes. Illumination with red light induces a chemical reaction in the cells of the changed skin, which leads to their destruction. The reaction is called ‚phototoxic reaction'.

2. What you need to know before you use Alacare

Alacare should be applied by a physician, a nurse or other health care professionals in one single session.

Do not use Alacare:

- if you are allergic to 5-aminolevulinic acid or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a certain disease of blood metabolism known as porphyria.
- if you were undergoing similar therapy with 5-aminolevulinic acid-containing preparations and it was unsuccessful.
- if you have other skin conditions caused by or made worse by exposure to light.

The success and assessment of treatment may be impaired if the treated area of the skin is further affected by:

- inflammation, infection, psoriasis, eczema or cancer
- tattoos

Warnings and precautions

Talk to your doctor before using Alacare:

- if you have dark brown or black skin or if you have very thick lesions since there is no experience with Alacare treatments in those cases.
- if you might be pregnant since treatment with Alacare is not recommended then.
- if you are receiving UV-therapy, it should be stopped before treatment with Alacare.

Your doctor or nurse will make sure that the Alacare plaster does not get into contact with your eyes.

As a general precaution, treated and surrounding skin should not be exposed to sunlight for about 48 hours following treatment.

Other medicines and Alacare

Inform your doctor if you use medicines that increase allergic or other harmful reactions after light exposure, such as:

- St. John's wort or its preparations: medicines to treat depression.
- griseofulvin: a medicine to treat fungal infections.
- medicines to increase water output through your kidneys with active substance names mostly ending in "thiazide" or "tizide".
- certain medicines to treat diabetes, such as glibenclamide, glimepiride.
- medicines to treat mental disorders, nausea or vomiting with active substance names mostly ending in "azine".
- medicines to treat bacterial infection with active substance names beginning with "sulfa" or ending in "oxacin" or "cycline".

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

Pregnancy and breast-feeding

Possible harmful effects and risks for a pregnancy and for the unborn child cannot be completely excluded at this time.

Alacare should not be used during pregnancy unless clearly necessary. Breast-feeding should be stopped for 48 hours after application of Alacare. Always ask your doctor for advice before taking any medicines.

Driving and using machines

Alacare has no known effect on the ability to drive and use machines.

3. How to use Alacare

It is important that you do not apply any cream to your scalp or face on the day of treatment before arriving for therapy at your doctor.

Adults (including the elderly)

Alacare plasters will be applied to your actinic keratoses (changed skin) for 4 hours in one single session. Afterwards these areas will be exposed to red light for a few minutes (photodynamic therapy). To protect your eyes from the intense light, you will be given goggles to wear during light exposure.

After treatment with plaster and illumination you should protect the skin from sunlight for 48 hours. Lesions should be checked by your doctor after three months.

Use in children and adolescents

Use of Alacare is not recommended, as there is no experience in treatment of children and adolescents below 18 years of age.

If you stop using Alacare

The effectiveness of the treatment might be reduced, if

- plaster application is stopped prematurely or
- light therapy is stopped too early.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects involving the treatment site (local side effects)

Almost all patients (99%) experience side effects localised to the treatment site (local side effects). These can occur during application of the Alacare plaster, during illumination of the treatment site and/or thereafter. Symptoms are usually of mild or moderate intensity. They rarely require early termination of illumination. For relief, the treated area can be cooled by a fan or similar during illumination. After therapy, local side effects persist for 1 to 2 weeks or occasionally longer.

Very common (more than 1 out of 10 patients):

- flaking
- irritation
- itching
- pain
- redness
- scab

Common (more than 1 out of 100 patients, but less than 1 out of 10 patients):

- areas of paleness or darkening of the skin
- bleeding
- blister
- discomfort
- erosion
- oedema (fluid accumulated in the tissue)
- peeling
- pustules (pimples)
- skin reaction
- secretion
- swelling

Uncommon (more than 1 out of 1000 patients, but less than 1 out of 100 patients):

- burn
- staining
- infection
- inflammation
- ulcer
- superficial skin defects

Side effects not involving the treatment site:

Common

- headache

Uncommon

- anxiety
- increased levels of the enzyme alanine aminotransferase
- nosebleed
- pustule (pimple like) rash
- staining of the skin

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In **United Kingdom**, you can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

In **Ireland**, you can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store Alacare

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

Use within 3 months after first opening.

After opening store plaster in the sachet in order to protect from light. After removal, the used plaster should be folded in half, adhesive side inwards so that the adhesive is not exposed, and then discarded safely. 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 Alacare contains

- The active substance is 5-aminolevulinic acid hydrochloride. Each medicated plaster of 4 cm^2 contains 8 mg 5-aminolevulinic acid (as hydrochloride), 2 mg per cm^2.

- The other ingredients are acrylic pressure sensitive adhesive, backing film, consisting of pigmented polyethylene and aluminium vapour coated polyester, release liner consisting of polyethyleneterephthalate film (to be removed before application).

What Alacare looks like and contents of the pack

Each medicated plaster has a size of 4 cm², is square with rounded corners and consists of a skin tone backing foil and a self-adhesive matrix, covered by a release liner which is removed prior to use. 4 plasters are sealed in a protective sachet.

Alacare is available in pack sizes of 4 or 8 plasters (1 or 2 protective sachet(s)) in a cardboard box.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

photonamic GmbH & Co. KG
Eggerstedter Weg 12
25421 Pinneberg
Germany

Manufacturer:

medac Gesellschaft
für klinische Spezialpraeparate mbH
Theaterstrasse 6
D-22880 Wedel
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Alacare
Denmark	Alacare
Finland	Alacare
France	Effala
Germany	Alacare
Ireland	Alacare
Italy	Alacare
Norway	Alacare
Poland	Alacare
Portugal	Alacare
Spain	Effala
Sweden	Alacare
UK	Alacare

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