

Alacare®

5-aminolevulinic acid (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Alacare.

This leaflet answers some common questions about Alacare. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Alacare against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Alacare is used for

The name of your medicine is Alacare. It contains the active ingredient 5-aminolevulinic acid (as hydrochloride).

Alacare is used to treat mild to moderate 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.

Your doctor, however, may prescribe Alacare for another purpose.

Ask your doctor if you have any questions about why Alacare has been prescribed for you.

This medicine is available only with a doctor's prescription and is to be

administered by a trained health care professional.

Before you use Alacare

When you must not use it

Do not use Alacare if you:

- are allergic (hypersensitive) to 5-aminolevulinic acid, acrylic pressure sensitive adhesive or any of the other ingredients of Alacare.
- suffer from a certain disease of blood metabolism known as porphyria.
- were undergoing similar therapy with 5-aminolevulinic acid-containing preparations and it was unsuccessful.
- have other skin conditions caused by or made worse by exposure to light.

Ask your doctor or pharmacist if you are not sure if this applies to you.

Treatment with Alacare may be less successful if your skin is affected by:

- inflammation
- infection
- psoriasis
- eczema
- cancer
- tattoos

Special care must be taken when using Alacare if you:

- have moderate brown to black skin
- have very thick lesions

How Alacare works in these cases has not been established.

Do not use Alacare for children and adolescents under 18 years of age.

The safety of Alacare in this age group has not been established.

Do not use Alacare after the expiry date (EXP) printed on the pack.

It may have no effect at all, or an entirely unexpected effect if you take it after the expiry date.

Do not use Alacare if the packaging is torn or shows signs of tampering, or if the patches do not look quite right.

If you are not sure whether you should use Alacare, contact your doctor.

Before you start to use it

You must tell your doctor if:

You are taking any of the following medicines:

- St John's Wort (*Hypericum perforatum*) - either by mouth (e.g. tablet), or directly onto your skin (e.g. cream or lotion).
- griseofulvin - a medicine for treating fungal infections
- thiazide diuretics - also known as fluid tablets - used to treat high blood pressure, heart failure or fluid retention e.g. hydrochlorothiazide
- sulfonylureas - used to treat diabetes - such as glibenclamide or glimepiride
- phenothiazines - used to treat mental disorders, or for nausea and vomiting - such as promethazine, prochlorperazine, chlorpromazine
- antibiotics that increase the risk of sun reactions - such as sulphonamides, quinolones or tetracyclines.

These medicines may increase allergic or other harmful reactions after light exposure.

You are receiving UV therapy.

This treatment should be stopped before using Alacare.

You are pregnant or are intending to become pregnant.

Your doctor will discuss the risks and benefits of using Alacare when pregnant.

You are breastfeeding or wish to breastfeed.

Breastfeeding should be stopped for 48 hours after using Alacare. Your doctor will discuss the risks and benefits of using Alacare while breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Alacare.

How to use Alacare

Use Alacare exactly as your doctor has prescribed.

The directions from your doctor may differ from the information contained in this leaflet.

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

How Alacare is used

Treatment will be provided by a trained health care professional. Alacare patches 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.

Alacare may not work as well if the patch is removed early or if the light therapy is stopped too early.

After treatment with patch and illumination you should protect the skin from sunlight for 48 hours.

Lesions should be checked by your doctor after three months.

If you use too much (overdose)

There has not been any reports of overdose of Alacare.

Nevertheless, reactions at the treatment site may be more pronounced if the Alacare patches are applied for much too long or the light treatment is used for much too long.

Contact the Poisons Information Centre (Australia - 13 11 26; New Zealand - 0800 POISON or 0800 764 766) for advice on the management of an overdose.

While you are using Alacare

Things you must do

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are using Alacare.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Tell your doctor if you become pregnant before using Alacare.

Alacare does not have any known effects on the ability to drive and use machines.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Like all medicines, Alacare may have unwanted side effects in some people.

Almost all patients experience some side effects localised to the treatment site. These can occur during application of the Alacare patch, during treatment with the light, or after the treatment. These side effects are usually mild or moderate, and

rarely need the treatment to be stopped.

Tell your doctor if you notice any of the following and they worry you:

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

Other side effects that have been reported to occur rarely include:

- burn
- staining
- infection
- inflammation
- ulcer
- superficial skin defects
- anxiety
- increased levels of the enzyme alanine aminotransferase
- nosebleed
- pustule (pimple like) rash
- staining of the skin

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Alacare

Storage

Keep Alacare where children cannot reach it.

Store below 25°C.

Use within 3 months of opening the sachet. After opening, store the patch inside the sachet to protect it from light.

Disposal

After removal, the used patch should be folded in half, adhesive side inwards so that the adhesive is not exposed, and then discarded safely.

Product Description

What it looks like

Alacare is a 2 x 2 cm skin coloured dermal patch which is self-adhesive. Four patches are sealed into a protective sachet. One or two sachets are packed into a cardboard carton.

Ingredients

Active ingredient:

Each dermal patch contains 8 mg 5-aminolevulinic acid (as hydrochloride)

Inactive ingredients:

Acrylic pressure sensitive adhesive, backing film, consisting of pigmented polyethylene and aluminium vapour coated polyester, release liner consisting of polyethylene terephthalate film (to be removed before application).

Alacare does not contain gluten, lactose, tartrazine or any other azo dyes.

Supplier

Alacare is supplied in Australia by:

Link Medical Products Pty Ltd
5 Apollo Street,
Warriewood NSW 2102
Australia

Alacare is supplied in New Zealand by:

Link Pharmaceuticals Ltd
Level 31, Vero Centre
48 Shortland Street
Auckland, 1140
New Zealand

Australian Registration Number

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