

Stieva-A[®] Cream

[Tretinoin 0.025% w/w, 0.05% w/w, 0.1% w/w]

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use Stieva-A Cream.

This leaflet answers some common questions about Stieva-A. It does not contain all of 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 expected benefits of you using Stieva-A Cream against the risks this medicine could 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 is Stieva-A Cream used for?

Stieva-A Cream is used to treat acne (spots).

Stieva-A belongs to a group of medicines called retinoids.

Stieva-A Cream helps to:

- Make your skin less oily
- Loosen blackheads and whiteheads so that they come out more easily
- Stop new blackheads, whiteheads and spots from forming
- Lowers the number of red, inflamed acne spots.

Stieva-A Cream is for use by adults and adolescents with acne.

It is not for use by children.

Your doctor may have prescribed Stieva-A Cream for another reason.

Stieva-A Cream is not addictive.

Before you use Stieva-A Cream

Do not use if:

You must not use Stieva-A Cream if:

- you have ever had an allergic reaction to tretinoin or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- **if you or any of your close family have had skin cancer**
- **if you are pregnant or trying to become pregnant**
- **if you are breast-feeding**
- **the expiry date (EXP) printed on the pack has passed**
- **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you are using any other medicines for acne.**

You may need to use the two products at different times of the day (eg. one in the morning and the other at bedtime).

- **you are taking any other medicines, including medicines you buy without a prescription.**

Stieva-A Cream can affect how other medicines work, or cause

skin irritation with other medicines. This includes

medicines containing benzoyl peroxide (also used to treat acne).

- **you are breastfeeding, pregnant or trying to become pregnant.**
- **you cannot tolerate or have skin reactions in sunlight or are allergic (hypersensitive) to tretinoin or any of the other ingredients of Stieva-A Cream**
- **you suffer from eczema, redness of the skin, broken blood vessels and tiny pimples usually on the central area of the face (rosacea), or redness and soreness around the mouth (perioral dermatitis).**

Stieva-A Cream may further irritate these conditions.

How do I use Stieva-A Cream?

How much to use

Use Stieva-A Cream as directed by your doctor or pharmacist.

- Use Stieva-A Cream once daily at night time over the whole of the affected area. Your doctor will tell you how many times to use the medicine.
- You should keep using the medicine until your doctor tells you otherwise.

How to apply it

Stieva-A Cream is for application to the skin only.

- **Wash your hands.**

- **Completely remove any make-up.**
- **Wash the affected area with a mild soap and warm water, and gently dry.**
- **Put a thin film of cream on the affected skin, using your fingertips, and smooth in.**
- **Apply to all of the area of your skin which has acne, not just each spot.**

Take care not to apply too much cream especially where it could run into your eyes, the angles of your nose, any skin folds, or other areas of the skin that do not require treatment.

Applying too much cream or applying it more frequently will not help your spots clear up more quickly, and may cause redness, peeling and discomfort. If this does happen, you may need to use a non-pore-clogging moisturiser (non-comedogenic) use the cream less often, or stop using it for a few days and then start again.

- **Wash your hands after using the cream.**

How long to use it for

- It can take 6 to 8 weeks before you see the full benefit of Stieva-A Cream.

Do not stop using Stieva-A Cream, or change the dose without first checking with your doctor.

Use in children and elderly patients

Stieva-A Cream is for use by adults and adolescents with acne.

It is not for use by children.

If you forget to use Stieva-A Cream

- **Don't apply a double dose to make up for forgotten doses.**
- **Apply the next dose at the usual time.**

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre call 131126 if you think you or anyone else may have used too much Stieva-A Cream, even if there are no signs of discomfort or poisoning.

The ingredients of Stieva-A Cream are not expected to be harmful if swallowed in the small amounts applied to the face. If you do accidentally get Stieva-A Cream in your mouth, rinse at once with plenty of water. Seek medical advice if you swallow a large amount.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Stieva-A Cream

Things you must do

Tell your doctor if, for any reason, you have not used your medicine exactly as directed.

Tell your doctor if you are pregnant or planning to become pregnant.

Use a reliable method of contraception properly while you are using Stieva-A Cream to prevent pregnancy.

If you do become pregnant during treatment with Stieva-A Cream, tell your doctor.

Breast-feeding is not recommended during treatment with Stieva-A Cream. Discuss with your doctor whether you choose to breast-feed or to use Stieva-A Cream.

Only use the cream on your skin. Keep it away from areas such as your mouth, lips, and eyes or inside your nose.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Stieva-A Cream to treat any other complaints unless your doctor says to.

Do not use the cream on any irritated areas of the skin, such as cuts, grazes, sunburn, or broken skin.

Do not use the cream on skin that has had cosmetic treatment such as depilation, chemical hair treatment, chemical peel, dermabrasion or laser resurfacing recently.

Do not use too much Stieva-A Cream on sensitive skin such as the neck, or allow it to accumulate in folds of your skin, including those between the nose and lips.

Avoid skin products that contain alcohol, spices or lime. These products may irritate your skin more if used with Stieva-A Cream.

Stieva-A Cream can cause increased sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun while using Stieva-A Cream. Use a sunscreen product and protective clothing to prevent sunburn.

Things to be careful of

Be careful driving or operating machinery until you know how Stieva-A Cream affects you.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to using Stieva-A Cream, even if the problem is not listed below.

Like other medicines, Stieva-A Cream can cause some side effects. If they occur, they are most likely to be minor and temporary. However,

some may be serious and need medical attention.

The most commonly reported side-effects are:

- redness of your skin
- skin flaking
- skin pain
- itching
- skin irritation
- skin tenderness
- burning feeling on the skin, especially when first applied
- stinging
- dry skin

These effects are normal. If they cause you a problem, try using Stieva-A Cream less often, or stop using it for a few days and then start again.

Other rare effects include:

- sensitivity to sunlight
- darkening of fair skin
- lightening of darker skin
- rash at the site of application
- swelling at the site of application
- allergic reaction
- skin thinning

Tell your doctor or pharmacist if any of the side effects become severe or troublesome, or if you notice any side effects not listed in this leaflet.

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**
- **Severe burning, peeling, or itching of your skin.**

Stop using Stieva-A Cream.

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.

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

How do I store Stieva-A Cream?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Stieva-A Cream 0.025% and 0.05% should be stored below 30°C.

Do not freeze.

Stieva-A Cream 0.1% should be stored below 25°C.

Do not leave in a car, on a window sill or in a bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

What Stieva-A Cream looks like

Stieva-A Cream comes in 25 g tubes containing 0.025% w/w, 0.05% w/w and 0.1% w/w tretinoin in a smooth light yellow cream.

Ingredients

Stieva-A Cream contains the active ingredient tretinoin.

Stieva-A Cream also contains butylated hydroxytoluene, butylated hydroxyanisole, disodium edetate, isopropyl palmitate, methyl hydroxybenzoate, PEG-40 stearate, propyl hydroxybenzoate, propylene glycol, purified water, stearic acid, stearyl alcohol, soft, white paraffin and titanium dioxide. Please note titanium dioxide is present in Stieva-A 0.1% cream formulation only.

Sponsor

Stieva-A Cream is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford Victoria 3067
Australia

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared on 2 September 2016.

The information provided applies only to: Stieva-A.

Stieva-A Cream 0.025%: AUST R 39837

Stieva-A Cream 0.05%: AUST R 39839

Stieva-A Cream 0.1%: AUST R 39838

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