

# STIEVA-A

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using STIEVA-A?

STIEVA-A contains the active ingredient tretinoin. STIEVA-A is a cream used to treat acne.

For more information, see Section [1. Why am I using STIEVA-A?](#) in the full CMI.

### 2. What should I know before I use STIEVA-A?

Do not use if you have ever had an allergic reaction to tretinoin or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Do not use this medicine if you are pregnant. This medicine should only be used by**

adolescents and adults, it should not be used in children.

For more information, see Section [2. What should I know before I use STIEVA-A?](#) in the full CMI.

**3. What if I am taking other medicines?**

Some medicines may interfere with STIEVA-A and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

**4. How do I use STIEVA-A?**

- Use STIEVA-A once daily at night all over the affected area.
- Only use STIEVA-A on the skin, do not ingest or swallow it.

More instructions can be found in Section [4. How do I use STIEVA-A?](#) in the full CMI.

**5. What should I know while using STIEVA-A?**

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, dentist or pharmacist you visit that you are using STIEVA-A.</li> </ul>
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<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine or change the dosage without first checking with your doctor.</li> <li>● Do not use this medicine if you are pregnant.</li> <li>● Do not use the cream on your mouth, lips, eyes or inside your nose.</li> <li>● Do not use this cream on skin that is irritated or damaged such as cuts, grazes, abrasions and sunburn.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how STIEVA-A affects you.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Store this medicine below 30°C. Do not freeze STIEVA-A.</li> </ul>

For more information, see Section [5. What should I know while using STIEVA-A?](#) in the full CMI.

## 6. Are there any side effects?

Side effects which have been reported include redness of your skin, skin flaking, skin pain, itching, skin irritation, skin tenderness, burning feeling on the skin (especially when first applied), stinging and dry skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# STIEVA-A

**Active ingredient(s):** *tretinoin*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using STIEVA-A. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using STIEVA-A.**

**Where to find information in this leaflet:**

- [1. Why am I using STIEVA-A?](#)
- [2. What should I know before I use STIEVA-A?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use STIEVA-A?](#)
- [5. What should I know while using STIEVA-A?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using STIEVA-A?

**STIEVA-A contains the active ingredient tretinoin.**

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

**STIEVA-A is used to treat acne (spots).**

STIEVA-A can help 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.
- lower the number of red, inflamed acne spots.

## **2. What should I know before I use STIEVA-A?**

### **Warnings**

#### **Do not use STIEVA-A if:**

- you are allergic to tretinoin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are pregnant or intend to become pregnant or are breastfeeding.
- you or anyone in your close family have had skin cancer.
- you are under the age of 12 (STIEVA-A is only for use in adolescents and adults).

#### **Check with your doctor if you:**

- have any other medical conditions.
- are allergic to foods, dyes, preservatives or any other medicines.

- have 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).
- take any medicines for any other condition.
- take any other medicines for your acne.

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

- cannot tolerate or have skin reactions in sunlight.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Tell your doctor immediately if you are pregnant or intend to become pregnant.

**You should not use STIEVA-A if you are pregnant.**

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**You must use a reliable method of contraception whilst using STIEVA-A.**

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with STIEVA-A and affect how it works. This includes medicines containing benzoyl peroxide which are also used to treat acne.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STIEVA-A.**

### **4. How do I use STIEVA-A?**

#### **How to use STIEVA-A**

- Use STIEVA-A once daily at night time over the whole of the affected area.
- Follow the instructions provided by your doctor or pharmacist and use STIEVA-A until your doctor tells you to stop.
- It can take 6 to 8 weeks before you see the full benefit of applying STIEVA-A to the affected area.

#### **How to apply STIEVA-A**

STIEVA-A is only for application to the skin. Do not swallow.



1. Wash your hands.
2. Completely remove any makeup if you are wearing it.
3. Wash the affected area with a mild soap and warm water and gently dry.
4. Put a thin film of cream on the affected skin using your fingers to smooth it in.
5. Apply to all areas of your skin where there is acne not just to the individual spots.

Take care not to apply too much STIEVA-A, 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 STIEVA-A or applying it too frequently will not help your acne clear up faster and it may cause redness, peeling and discomfort.

If this happens, you may need to use a non-pore-clogging moisturiser (non-comedogenic), use STIEVA-A less often or stop using it for a few days and then start again.

6. Wash your hands after using STIEVA-A.

## **If you forget to use STIEVA-A**

STIEVA-A should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much STIEVA-A**

If you think that you have used too much STIEVA-A, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

## **5. What should I know while using STIEVA-A?**

### **Things you should do**

**Tell your doctor straight away if you:**

- have not used STIEVA-A as directed

- think you may be or are pregnant and stop using STIEVA-A immediately
- are breastfeeding

Remind any doctor, dentist or pharmacist you visit that you are using STIEVA-A.

## **Things you should not do**

- Do not stop using this medicine or change how much you use without first checking with your doctor.
- Do not use the cream on your mouth, lips, eyes or inside your nose.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.
- Do not use STIEVA-A to treat any other complaints unless your doctor tells you to.
- Do not use this cream on skin that is irritated or damaged such as cuts, grazes, abrasions and sunburn.
- Do not use cream on skin that has had cosmetic treatment such as depilation, chemical hair treatment, chemical peel, dermabrasion or laser resurfacing.
- Do not use too much STIEVA-A on sensitive skin such as the neck or allow it to accumulate in the folds of your skin including between the nose and lips.
- Avoid skin products that contain alcohol, spices or lime.

These products may irritate your skin more if used together with STIEVA-A.

## **Things to be careful of**

- STIEVA-A can cause increased sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun.

Use sunscreen and protective clothing to prevent sunburn.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how STIEVA-A affects you.**

## **Looking after your medicine**

- Keep the cream in the tube until it is time to use it.
- Do not put STIEVA-A in the freezer.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Skin related</b> <ul style="list-style-type: none"><li>• redness of your skin</li><li>• skin flaking</li><li>• skin pain</li><li>• itching</li><li>• skin irritation</li><li>• skin tenderness</li><li>• burning feeling on the skin, especially when first applied</li><li>• stinging</li><li>• dry skin</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<p>These effects are normal. If they cause you a problem, try using STIEVA-A less often or stop using it for a few days and then start it again.</p> <ul style="list-style-type: none"> <li>● sensitivity to sunlight</li> <li>● darkening of fair skin</li> <li>● lightening of dark skin</li> <li>● rash at the site of application</li> <li>● swelling at the site of application</li> <li>● skin thinning</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction</b></p> <ul style="list-style-type: none"> <li>● signs include wheezing, difficulty in breathing, swelling of the lips, mouth or tongue, hay fever, a lumpy rash</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>(hives) on the skin, fainting</p> <p><b>Skin related</b></p> <ul style="list-style-type: none"> <li>• severe burning, peeling or itching of your skin</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

## What STIEVA-A contains

<b>Active ingredient (main ingredient)</b>	tretinoin
<b>Other ingredients (inactive ingredients)</b>	butylated hydroxyanisole butylated hydroxytoluene disodium edetate isopropyl palmitate methyl hydroxybenzoate PEG-40 stearate propyl hydroxybenzoate propylene glycol purified water stearic acid stearyl alcohol white soft paraffin
<b>Potential allergens</b>	methyl hydroxybenzoate propyl hydroxybenzoate

**Do not take this medicine if you are allergic to any of these ingredients.**



## **What STIEVA-A looks like**

STIEVA-A is a white to light yellow cream.

0.025% - AUST R 39837 available in a 3 g or 25 g tube.

0.05% - AUST R 39839 available in a 25 g tube.

## **Who distributes STIEVA-A**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford VIC 3067

Australia

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