

Winlevi

Clascoterone

1% (10 mg/g) cream

What is in this leaflet

This leaflet provides important information about using WINLEVI. **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 WINLEVI.**

Where to find information in this leaflet:

1. Why am I using WINLEVI?
2. What should I know before I use WINLEVI?
3. What if I am taking other medicines?
4. How do I use WINLEVI?
5. What should I know while using WINLEVI?
6. Are there any side effects?
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1. Why am I using WINLEVI?

WINLEVI contains the active ingredient clascoterone. WINLEVI is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years of age and older.

WINLEVI belongs to a group of medicines called androgen receptor inhibitors. The exact mechanism of action of WINLEVI for the topical treatment of acne vulgaris is unknown.

2. What should I know before I use WINLEVI?

Warnings

Do not use WINLEVI if:

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

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

Check with your doctor if you:

- Have any other medical conditions; in particular skin problems, including eczema, cuts or sunburn
- Take any medicines for any other condition.

Other warnings you should know about:

- WINLEVI is to be used on the skin only (topical). Do not use WINLEVI in or on your eyes, mouth, or vagina.
- Avoid getting WINLEVI into your eyes, lips, mouth, corners of the nose, or mucous membranes. If contact with mucous membranes happens, rinse immediately and thoroughly with water.
- Avoid using skin products that may dry or irritate your skin such as:
 - medicated or abrasive soaps and cleansers
 - soaps, cleansers, and cosmetics that have strong skin drying effects
 - products that contain high amounts of alcohol, astringents, spices, or lime.
- Do not use WINLEVI for a condition for which it was not prescribed.
- Do not give WINLEVI to other people, even if they have the same symptoms you have. It may harm them.

Symptoms of a disorder where the adrenal gland does not make enough of certain hormones have been observed during treatment with WINLEVI. Your healthcare professional may stop your treatment with WINLEVI if you develop any adrenal problems.

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. WINLEVI should not be used during pregnancy.

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

It is not known if WINLEVI cream is safe and effective in children under 12 years of age.

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.

No drug interaction studies have been conducted with WINLEVI, therefore, interactions with other drugs have not been established.

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

4. How do I use WINLEVI?

How to use WINLEVI

Use WINLEVI exactly as your healthcare professional tells you to use it.

Before applying WINLEVI, gently wash and dry the entire area of the skin to be treated.

Apply a thin even layer of WINLEVI over the entire area prone to acne, twice a day, in the morning and in the evening. For optimal effectiveness, do not spot treat.

Wash your hands after applying WINLEVI.

If you forget to use WINLEVI

If you forget to apply a dose, the next dose should be applied at the usual time. Apply the same amount you usually would. Do not apply extra.

If you use too much WINLEVI

If you think that you have used too much WINLEVI, you may need urgent medical attention.

You should immediately:

- In Australia: phone the Poisons Information Centre on **13 11 26**
- In New Zealand: phone the National Poisons Centre on **0800 POISON (0800 764 766)**, 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.

5. What should I know while using WINLEVI?

Remind any doctor, dentist or pharmacist you visit that you are using WINLEVI.

Driving or using machines

The effects of WINLEVI on a person's ability to drive and use machines were not assessed as part of its registration.

Looking after your medicine

- Store WINLEVI at room temperature (below 25°C).
- Do not freeze.

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

Keep it where young children cannot reach it.

When to discard your medicine

Please return any unused portion to your pharmacist 6 months after the date of dispensing.

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. It is recommended that WINLEVI not be disposed of in household waste or wastewater.

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.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <i>Common side effect</i> <u>Local skin irritation:</u> <ul style="list-style-type: none">• Itching• Burning• Skin redness• Peeling, scaling or dryness <u>Infections and infestations:</u> <ul style="list-style-type: none">• Inflammation of the nose and throat <i>Side-effects common in patients 12 to 18 years old:</i> <u>General disorders</u> <ul style="list-style-type: none">• Headache• Inflammation of the nose and throat <i>Rare side effects:</i> <u>Gastrointestinal conditions</u> <ul style="list-style-type: none">• Vomiting• Upper abdominal pain <u>Infections and infestations</u> <ul style="list-style-type: none">• Infection of the airways and the lungs• Inflammation of the sinuses• Throat infection <u>Administration side conditions</u> <ul style="list-style-type: none">• Application site dryness <u>Reproductive system and breast disorders</u> <ul style="list-style-type: none">• Period pain <u>Hair colour changes</u> | Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you. |

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:

Australia: you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

New Zealand: you can report any suspected adverse reactions via <https://pophealth.my.site.com/carmreportnz/s/>.

Adverse effects can also be reported to customerservice.aus@sunpharma.com, or Australian Toll Free: 1800 726 229 or New Zealand Toll Free: 0800 726 229.

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

7. Product details

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

What WINLEVI contains

| | |
|--|---|
| Active ingredient (main ingredient) | Clascoterone |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• Cetyl alcohol• Citric acid monohydrate• Disodium edetate• dl-alpha-tocopherol• mono- and di-glycerides• liquid paraffin• polysorbate 80• propylene glycol• purified water |

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

What WINLEVI looks like

WINLEVI is a white to almost white cream.

WINLEVI is supplied in tubes 2 g, 10 g, 30 g and 60 g. Not all pack sizes may be marketed.

New Zealand Sponsor

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