

WINLEVI[®] (Clascoterone)

1% Cream

Clascoterone 1% Cream

Consumer Medication Information Leaflet (RiMUP)

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1. What Winlevi[®] is used for
Winlevi[®] cream is a prescription medicine used on the skin (topical) to treat acne vulgaris in people 12 years of age and older.

2. How Winlevi[®] works

Winlevi[®] contains of *clascoterone* is an androgen receptor inhibitor. The mechanism of action for the topical treatment of acne vulgaris is unknown..

3. Before you use Winlevi[®]

When you must not use it

Do not use Winlevi[®]:

- on skin areas with cuts, abrasions, eczema or on sunburned skin.
- if you are pregnant or plan to become pregnant. It is not known if Winlevi[®] cream will harm your unborn baby
- if you are breastfeeding or plan to breastfeed. It is not known if Winlevi[®] cream passes into your breast milk.
- Do not use Winlevi[®] cream in or on your eyes, mouth, or vagina.
- If you are below 12 years of age

Before you start to use it

Pregnancy and Breast-feeding

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding. The use of

Winlevi[®] in pregnant or breast-feeding women is not recommended.

Hypothalamic-pituitary-adrenal (HPA) axis suppression

Use of Winlevi[®] may affect adrenal gland function (i.e. does not make enough of certain hormones) Your healthcare provider may stop your treatment with Winlevi[®] if you develop any adrenal problems.

Important information about some of the ingredients of Winlevi[®]

Winlevi[®] does not contain any ingredients which would influence the safe and effective use of the product.

Use in children

Winlevi[®] is not recommended to be used in children younger than 12 years old.

Use in elderly

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range

Taking other medicines

Winlevi[®] does not usually interfere with other medicines.

However, you should always tell your doctor or pharmacist about all medicines you are taking or planning to take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

4. How to use Winlevi[®]

How much and when to use it

Winlevi[®] is intended for use on the skin only (topical).

Always use Winlevi[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you have doubts.

Before applying Winlevi[®] cream, gently wash and dry the affected skin area.

After the skin is dry, apply a thin even layer of Winlevi[®] cream to the affected areas 2 times each day, in the morning and the evening.

Wash your hands after applying Winlevi[®] cream.

How long to use it

Your doctor will tell you how long your treatment with Winlevi[®] will last.

Do not stop using Winlevi[®] without telling your doctor or pharmacist. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. Just continue your next dose.

If you use too much (overdose)

If accidentally swallowed / taken Winlevi[®] orally, inform your doctor immediately or go to the nearest hospital.

If Winlevi[®] comes into contact with mucous membranes (i.e. eyes, lips, mouth, corners of nose, etc) rinse well with water.

5. While you are using Winlevi[®]

Things you must do

Follow your doctor's instruction when you are taking Winlevi[®]

Things you must not do

Do not use Winlevi[®] after the expiry date which is stated on the outer carton and tube.

Do not stop using the medicine unless advised by your doctor.

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Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Winlevi® to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- if you are have skin problems, including eczema, cuts or sunburn
- Winlevi® does not usually interfere with other medicines. However, you should always tell your doctor or pharmacist about all medicines you are taking or planning to take, including any obtained without a prescription.
- the safety & efficacy of Winlevi® in pregnancy and breastfeeding women has not been established, therefore, as with all new drugs, its use is not recommended.
- If you have symptoms of a disorder where the adrenal gland does not make enough of certain hormones (adrenal insufficiency) during treatment with Winlevi®. Your healthcare provider may stop your treatment with Winlevi® if you develop any adrenal problems.

6. Side effects

Like all medicines, Winlevi® can cause side effects although not everybody gets them.

Common (from 1 in 100 to 1 in 10):

- local skin irritation including itching, burning,

skin redness or peeling.

- symptoms of a disorder where the adrenal gland does not make enough of certain hormones (adrenal insufficiency)

If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines(AEFI)].

7. Storage and disposal of Winlevi®:

Keep out of the reach and sight of children.

Prior Opening: Store the product in a refrigerator between 2°C and 8°C. Do not freeze.

After Opening: Store at or below 30°C, away from direct sunlight and heat.

Discard unused portion after one month from first opening.

Do not use Winlevi® after the expiry date stated on the label after 'Exp'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product description

What it looks like

Winlevi® cream 1% is supplied in an epoxy-lined aluminum blind-end tube with a polypropylene cap closure.

Pack sizes: tube of 2gm, 10gm, 30gm and 60gm

Ingredients

The active ingredient is *clascoterone*

The other ingredients are: *cetyl alcohol, citric acid monohydrate, edetate disodium, mineral oil, mono- and di-glycerides, polysorbate 80, propylene glycol, purified water, and vitamin E*

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9. Manufacturer

Cosmo S.P.A.
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10. Product registration holder

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11. Date of revision

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