

Package leaflet: Information for the patient

Winlevi® 10 mg/g cream

clascoterone

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Winlevi is and what it is used for
2. What you need to know before you use Winlevi
3. How to use Winlevi
4. Possible side effects
5. How to store Winlevi
6. Contents of the pack and other information

1. What Winlevi® is and what it is used for

Winlevi contains the active substance clascoterone that belongs to a group of medicines known as ‘anti-acne preparations for topical use’. The exact way that Winlevi works is not known. It is thought to treat acne by blocking androgens in your skin from making too much sebum (oils that keep your skin moist).

Winlevi is used for the skin (topical) treatment of *acne vulgaris* in adults and adolescents aged 12 years and older.

2. What you need to know before you use Winlevi®

Do not use Winlevi

- if you are allergic to clascoterone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your doctor before using Winlevi
- For topical and external use only.
- Do not use in eyes, mouth or vagina.
- Do not apply to other skin problems, cuts, abrasions, eczema or on sunburnt skin.
- Avoid getting this medicine in your eyes, lips, mouth, corners of the nose or mucous membranes. If contact with mucous membranes happens, rinse well 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 (used to dry or shrink skin tissue), spices, or lime
- You may experience adrenal suppression as a rare side effect of taking Winlevi. This is where the adrenal gland does not make enough of certain hormones. Some people have no symptoms unless

they are exposed to stress. If you experience a medical emergency (such as an infection) or have surgery, tell your healthcare professional that you are taking Winlevi. Adrenal suppression may cause further issues in these cases. See the “Serious side effects and what to do about them” table (refer to section 4).

Children and adolescents

Do not give this medicine to children under twelve years. It is not known if it works or if it is safe for them.

Other medicines and Winlevi

Tell your doctor if you are using, have recently used or might use any other medicines. Whether, you were previously or are currently taking corticosteroid drugs.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If the chest/breasts is/are subject to treatment with Winlevi, do not breast-feed your baby.

Driving and using machines

Winlevi has no or negligible influence on the ability to drive and use machines.

Winlevi contains cetyl alcohol.

May cause local skin reactions (e.g. contact dermatitis).

Winlevi contains propylene glycol.

This medicine contains 250 mg propylene glycol in each application which is equivalent to 25 % w/w. Propylene glycol may cause skin irritation.

3. How to use Winlevi®

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not give Winlevi to other people, even if they have the same symptoms you have. It may harm them.

Winlevi is to be used on the skin only (topical). Do not use Winlevi in or on your eyes, mouth or vagina.

Before applying this cream, gently wash and dry the affected skin area. Apply a thin, uniform layer of approximately 1 gram, corresponding to 2 fingertip units to the affected area twice a day, once in the morning and once in the evening. When spread on the skin, this should be enough to cover the size of two adult palms or one adult face. Wash your hands after applying the cream.

Contact your doctor at 12 weeks, as it is required to re-evaluate your treatment and decide whether it is necessary to continue or restart treatment after this period.

Use in adults and adolescents

Apply a thin, uniform layer to the affected area twice a day, once in the morning and once in the evening.

If you use more Winlevi than you should on your skin, you will not get rid of your acne any quicker, but your skin may become irritated and red. Contact a healthcare professional, even if there are no symptoms.

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 stop using Winlevi

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very Common (may affect more than 1 in 10 people)

Redness of the skin
Skin scaling
Skin dryness

Common (may affect up to 1 in 10 people)

Itching
Stinging/burning sensations
Swelling
Stretch marks (striae rubrae)
Spider veins (telangiectasia)
Skin thinning (skin atrophy)

Rare (may affect up to 1 in 1,000 people)

Polycystic ovaries
Absence of menstruation (amenorrhea)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Adrenal effects (may include one or several): Unexplained fatigue, weakness, nausea, stomach pain, or joint / muscle pain	√		
Adrenal effects (may include one or several): Unexplained weight loss, absence of menstruation, vomiting, impaired memory, depression, or altered mental state (psychosis). Talk to your healthcare professional if these symptoms appear, but you're not sure why.		√	

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.co.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Winlevi®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Do not freeze.

Prior to dispensing:

Store in a refrigerator (2°C-8°C).

After dispensing (receiving this medicine from your pharmacist):

Do not store above 25°C.

Discard the unused product 180 days after the date of dispensing or 6 months after first opening, whichever comes first.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Winlevi contains

- The active substance is clascoterone.
- The other ingredients are cetyl alcohol, citric acid monohydrate (E330), glycerol monostearate 40-55 Type I, liquid paraffin, polysorbate 80, propylene glycol (E1520), purified water, disodium edetate, all-*rac*- α -tocopherol (E307).

What Winlevi looks like and contents of the pack

Winlevi is a white to almost white cream.

Winlevi is available in tubes containing 10 g, 30 g or 60 g of cream.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2-B Draycott Avenue,
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Manufacturer

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For information in large print, tape, CD or Braille, telephone 0800 198 5000

Please be ready to give the following information:

Product name	Reference Number
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Winlevi 10 mg/g cream	PL 25258/0425
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This leaflet was last revised in January 2025.