

GENIMOD®
5% Cream

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about GENIMOD

GENIMOD cream is a topical preparation containing 5% imiquimod with the following excipients: polysorbate, glycerin, sodium metabisulfite, emulsifying wax, vaseline, and potassium sorbate.

Imiquimod is an immune response modifier.

GENIMOD cream is indicated in topical treatment of the following conditions:

- External genital and perianal warts (condylomata acuminata) in adults.
- Small superficial basal cell carcinomas in adults.
- Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.

The way to use GENIMOD

Use according to your doctor's instructions.

The application frequency and duration of treatment with imiquimod cream is different for each indication.

Wash and dry your hands carefully before and after applying the cream.

Wash the treatment area with mild soap and water and dry thoroughly before applying the cream.

Do not cover the treated area with bandages or other dressings after you have applied the cream.

Indication	Dosage
External genital warts in adults	-Apply a thin layer of the cream on affected areas 3 times per week (ex: Monday, Wednesday, Friday) before bedtime; avoid any application on internal surfaces. -Rub gently into the skin until the cream vanishes. -Keep the cream on the warts for 6 to 10 hours; do not shower or bathe during this time; after that wash the area where the cream was applied with mild soap and water. -Men with warts under the foreskin should pull the foreskin back each day and wash underneath it. -Continue the use of this cream until the clearance of the warts or for a maximum of 16 weeks per episode of warts.
Superficial basal cell carcinoma in adults	-This cream should be applied for 6 weeks, 5 times per week (ex: Monday to Friday) before bedtime, and leave on the skin for approximately 8 hours; do not shower or bathe during this time; after that wash the area where the cream was applied with mild soap and water. -Apply this cream to the affected area and 1cm around the affected area; Rub gently into the skin until the cream vanishes. -Response to the treatment should be assessed 12 weeks after the end of treatment; in case of incomplete response, a different therapy should be used.

Actinic keratosis in adults	- Sufficient cream should be applied to cover the affected area 3 times per week (ex: Monday, Wednesday, Friday) for 4 weeks before bedtime. -Rub gently into the skin until the cream vanishes. -Leave the cream on the skin for 8 hours; do not shower or bathe during this time; after that wash the area where the cream was applied with mild soap and water. - The skin will be assessed after 4 weeks of finishing the treatment; If the lesions have not all disappeared, further 4 weeks of treatment may be necessary
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In case of overdose

Wash the extra away with mild soap and water. If you suspect an overdose, irritation develops, or if the drug has been ingested, inform your doctor at once and seek emergency medical attention.

In case of missed dose

Apply the missed dose as soon as you remember and continue with the regular schedule. This cream should not be applied more than once daily.

Contraindications

This drug is contraindicated in case of hypersensitivity to any of the ingredients

Precautions

- Avoid contact with the eyes, lips and nostrils.
- This cream may exacerbate inflammatory conditions of the skin.
- Use caution in patients with autoimmune conditions, in organ transplant patients, and in patients with reduced hematological reserve.
- This cream shouldn't be used until the area to be treated has healed after previous drug or surgical treatment.
- An interruption of dosing should be considered in case of appearance of local inflammatory reactions and other general disorders after using this cream.
- If the treated site becomes too uncomfortable, wash the cream off with mild soap and water. As soon as the problem has stopped you may restart to apply the cream.
- Treating urethral, intra-vaginal, cervical, rectal or intra-anal warts is not recommended.
- Imiquimod cream therapy should not be initiated in tissues where open sores or wounds exist until after the area has healed.
- When being treated for genital warts, this cream should be washed from the skin before sexual activity. Imiquimod cream may weaken condoms and diaphragms, therefore concurrent use with imiquimod cream is not recommended. Alternative forms of contraception should be considered.
- Repeated treatment with this cream is not recommended in immunocompromised patients.
- This cream has not been shown effective in HIV positive patients.
- Follow these additional recommendations when being treated for Superficial basal cell carcinoma and Actinic keratosis: do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with this cream. Wear protective clothing and wide brimmed hats when outdoors; the treated area is likely to appear different from normal skin.
- Ask your doctor before using this medication in case of pregnancy or lactation.
- There are no data available on the use of imiquimod in children and adolescents in the approved indications.

Associations with other medications

Please inform your doctor if you are using any other medication.

This cream should be used with caution in patients who are receiving immunosuppressive medication.

Adverse reactions

The most commonly reported adverse reactions include: infections, pustules, lymphadenopathy, anorexia, headache, nausea, myalgia, arthralgia, back pain, fatigue, and application site reactions. Other adverse reactions have also been reported.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children. Do not freeze. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

GENIMOD, imiquimod 5% cream, tube of 5 g

Issue date: 08/2019

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