

Dermatica

Package leaflet: Information for the user Tretinoin, Niacinamide and Clindamycin Lotion

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, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their skin condition is similar to yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.
- Make sure to follow the advice on the dispensing label provided, and use the product before the expiry date printed on the bottle.

What is in this leaflet:

1. What are **Tretinoin, Niacinamide and Clindamycin** and what they are used for
2. What you need to know before you use **Tretinoin, Niacinamide and Clindamycin**
3. How to use **Tretinoin, Niacinamide and Clindamycin**
4. Possible side effects
5. How to store **Tretinoin, Niacinamide and Clindamycin**
6. Contents of the pack and other information

1. What are Tretinoin, Niacinamide and Clindamycin and what they are used for

This combination is used topically to treat acne vulgaris.

Tretinoin is a retinoid that reduces acne breakouts .

Niacinamide is an active form of vitamin B3. It reduces inflammation and redness, and also helps fade dark marks left by acne breakouts.

Clindamycin is an antibiotic. It limits the growth of bacteria associated with acne and associated inflammation.

Combining these active substances can help target and improve different skin concerns simultaneously.

2. What you need to know before you use Tretinoin, Niacinamide and Clindamycin

NEVER USE TREATMENT IF YOU ARE ALLERGIC TO TRETINOIN, NIACINAMIDE, CLINDAMYCIN OR ANY OF THE OTHER INGREDIENTS FOUND IN TRETINOIN, NIACINAMIDE AND CLINDAMYCIN LOTION.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR doctor, nurse or pharmacist.

Warnings and precautions

- Avoid contact of the product with eyes, eyelids, nostrils, mouth, sore, broken or inflamed skin. In case of accidental contact, wash thoroughly with water.
- This formulation is not suitable for anyone under the age of 16 years, or anyone who has not been directly prescribed the treatment.

- Cold and windy weather may further irritate the skin. Make sure to apply moisturiser regularly to the skin to help reduce irritation.
- If you have already been using exfoliating products or other prescription treatments on the face, discontinue use and wait until skin irritation has ceased before starting this treatment.
- Make sure to use sun protection using a sunscreen with an SPF factor of at least 30, with UVA and UVB protection. Avoid exposure to too much sun or other sources of UV radiation such as sunbeds.
- Avoid the use of additional astringent, desiccant or irritant cleansing cosmetics, or scented or alcoholic products that may cause additional irritation.
- You can use make-up products and moisturisers of your choice. We recommend non-comedogenic tested products (ask your doctor, nurse or pharmacist for advice).
- Avoid laser, aesthetics and waxing treatments while using this product simultaneously. Speak to your doctor, pharmacist or practitioner about suitable alternative options or taking a temporary break from using the product.
- If the product leads to irritation such as burning, redness or dryness, discontinue use until the symptoms have settled before gradually reintroducing.
- If you have eczema, psoriasis, perioral dermatitis on the face and your symptoms worsen after using this treatment, stop immediately and speak to your prescriber.
- Contact your doctor, nurse or pharmacist if you have a history of skin cancer on the face before using this product.
- Do not use if you have inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis) or a history of colitis with past antibiotic use which is characterised by prolonged or significant diarrhoea or abdominal cramps.
- If prolonged or significant diarrhoea and/or abdominal cramps occur whilst using this product, discontinued and seek medical attention immediately.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR doctor, nurse or pharmacist FOR ADVICE.

Other medicines

Inform your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription..

Pregnancy and breastfeeding

If you are pregnant or think you may be pregnant, do not use **Tretinoin, Niacinamide and Clindamycin**. Using **Tretinoin, Niacinamide and Clindamycin** whilst pregnant may be harmful to the unborn child. Talk to your doctor, you will discuss other treatments.

If you are breastfeeding, tell your doctor before treatment with **Tretinoin, Niacinamide and Clindamycin**.

Driving and using machines

Tretinoin, Niacinamide and Clindamycin are unlikely to have an effect on the ability to drive or operate machines.

3. How to use your formula

- Use formula once daily at night as directed on the dispensing label provided with the formula.
- Wash your face gently with a mild cleanser and warm water and pat your skin dry with a towel.
- Apply a thin layer of product (one to two pumps)
- Dab the cream on your forehead, chin, nose and both cheeks, and then gently spread it evenly over your whole face avoiding the skin on and around the eyes and mouth.
- Wash hands thoroughly after application.
- Allow the product to settle before applying an occlusive moisturiser to finish.

Cautions

- Do not apply to sore or broken skin.
- For external use only.
- Check the expiry date on the formula and discard use if it has expired.

If you use more formula than recommended

You will not get faster or better results by using more formula than recommended. If you have accidentally applied too much formula, wash the face with a mild cleanser and warm water to remove.

If you forget to apply your formula

If you accidentally forget an application, apply the next application as normal. Do not apply additional to make up for the missed dose.

Consult your prescriber if no improvement is seen after three months, or if continued irritation occurs.

IN ALL CASES, STRICTLY FOLLOW THE INSTRUCTIONS FROM YOUR DOCTOR, NURSE OR PHARMACIST.

4. What are the possible side effects

Like all medicines, **Tretinoin, Niacinamide and Clindamycin** can cause side effects in some people. Local side effects may occasionally occur in the form of irritation, redness, a tingling sensation, dryness and slight peeling of the skin.

These effects which are related to the intended action of the product can be tolerated by reducing the quantity of lotion applied to the skin as well as by a reduction in the frequency of application of the lotion.

In the first weeks of treatment, a worsening of acne may be observed, including the appearance of small white pustules. This reaction is normal and is a sign the treatment has begun to work. If you have any concerns, inform your doctor, nurse or pharmacist.

Due to the presence of alcohol, frequent applications on the skin can cause irritation and dryness of the skin.

Common: seen in between one in 10 and one in 100 users

Reddening, peeling, scaling and swelling of the skin. Dry skin, itching, a warmth, stinging, burning or painful sensation. Rashes may occur. Temporary changes (increase or decrease) in skin pigmentation may occur. If any of these symptoms are severe, or if you develop crusts, blisters, swelling or a burning sensation on the skin, stop using the lotion and consult your doctor, nurse or pharmacist immediately.

Uncommon: seen in between one in 1000 and one in 100 users

Irritation of the eye and swelling. Blistering and crusting of the skin.

Very rare: seen in up to one in 10,000 users

Contact allergy has been reported with medicines containing **Tretinoin, Niacinamide and Clindamycin**.

DO NOT HESITATE TO ASK THE ADVICE OF YOUR DOCTOR, NURSE OR PHARMACIST.

If you experience any undesirable effects, talk to your doctor, nurse or pharmacist. This also applies to any undesirable effect that is not mentioned in this leaflet.

Reporting of side effects

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should talk to your doctor, nurse pharmacist or other healthcare professional.

For UK patients: You can help make sure medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.mhra.gov.uk/yellowcard alternatively you can call Freephone 0800 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

For USA patients: You may report serious side effects or adverse reactions to the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch

5. How to store Tretinoin, Niacinamide and Clindamycin Lotion

Keep this medicine out of sight and reach of children.

Do not use **Tretinoin, Niacinamide and Clindamycin** after the expiry date which is stated on the carton.

Do not store above 25°C/77°F. Store in a cool, dry place away from moisture and direct sunlight.

Medicines should not be disposed of in wastewater or household rubbish. Your formula pump is recyclable once there is absolutely no product left, but medicines should not be disposed of in wastewater or household rubbish. Dispose of remaining medicine at a local pharmacy who can safely dispose of it, helping to protect the environment.

6. Contents of the pack and other information

The active substances are:

Tretinoin 0.015 g /0.025 g /0.05 g /0.1 g, **Niacinamide** 4 g and **Clindamycin** 1 g (as clindamycin hydrochloride) in 100 g of lotion

The other ingredients are:

Purified Water, Propylene Glycol, Glycerin, Panthenol, Cetyl Alcohol, Glyceryl Stearate, Isohexadecane, Isododecane, C13-C15 Alkane, Dimethicone, Propanediol, Polyacrylate-13, Polyisobutene, Polysorbate 20, Polyurethane-39, Phenoxyethanol (0.6%), Tocopheryl Acetate, Ceramide AP, Ceramide EOP, Ceramide NP, Phytosphingosine, Cholesterol, Sodium Lauroyl Lactylate, Xanthan Gum, Carbomer, Sodium Hyaluronate

This medicine comes in the form of lotion.
Pump contains 12.5ml, 15ml, 25ml or 30ml of lotion.

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