

# Dermatica

## Package leaflet: Information for the user Tretinoin, Azelaic Acid and Tranexamic acid 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.
- This leaflet applies to all strengths of **Tretinoin** combined with **Azelaic Acid and Tranexamic acid** supplied. To identify which strength of lotion you have been supplied with, see label printed on the treatment bottle.

#### What is in this leaflet:

1. What **Tretinoin , Azelaic Acid and Tranexamic acid** is and what it is used for
2. What you need to know before you use **Tretinoin , Azelaic Acid and Tranexamic acid**
3. How to use **Tretinoin , Azelaic Acid and Tranexamic acid**
4. Possible side effects
5. How to store **Tretinoin , Azelaic Acid and Tranexamic acid**
6. Contents of the pack and other information

#### 1. What Tretinoin , Azelaic Acid and Tranexamic acid is and what it is used for

For the topical treatment of mottled hyperpigmentation, roughness and fine wrinkling of photodamaged skin due to chronic sun exposure. Can also be used for local treatment of acne of medium severity.

**Tretinoin** works by increasing the skin cell turnover rate, which helps exfoliate the skin and improve the signs of photodamage.

**Azelaic acid** and **Tranexamic acid** helps reduce areas of hyperpigmentation, evening out overall skin tone.

These active substances are more effective when combined than when used separately.

#### 2. What you need to know before you use Tretinoin , Azelaic Acid and Tranexamic acid

**NEVER USE TREATMENT IF YOU ARE ALLERGIC TO TRETINOIN, AZELAIC ACID, TRANEXAMIC ACID OR ANY OF THE OTHER INGREDIENTS FOUND IN TRETINOIN, AZELAIC ACID AND TRANEXAMIC ACID LOTION.**

**If any of these apply to you, go back to your doctor without using Tretinoin, Azelaic Acid and Tranexamic acid lotion.**

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

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

#### IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

#### Warnings and precautions

- Avoid contact of the lotion with eyes, eyelids, nostrils, mouth. In case of accidental contact, wash thoroughly with water. • Not suitable for use under the age of 16 years. • Cold and windy weather may irritate skin treated with **Tretinoin, Azelaic acid and Tranexamic acid**. If you have already been treated with other local exfoliating products prior to treatment, wait until skin irritation has ceased before starting 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 by selecting from non-comedogenic tested products (ask your doctor or pharmacist for advice).
- Avoid waxing while using this product simultaneously due to irritation.
- Speak to your prescriber or practitioner if you are undergoing facial skin treatments such as laser, microneedling, chemical peels or other procedures not listed.
- 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 facial skin cancer before using this product.
- Worsening of asthma in patients treated with azelaic acid has been reported rarely during post-marketing surveillance. If you experience a worsening of asthma, discontinue use and notify your doctor and pharmacist immediately.

#### IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

#### Other medicines and Tretinoin , Azelaic Acid and Tranexamic acid

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

#### Pregnancy and breastfeeding

If you are pregnant, trying to conceive, or breastfeeding do not use **Tretinoin, Azelaic Acid and Tranexamic Acid**. Using **Tretinoin, Azelaic Acid and Tranexamic Acid** whilst pregnant may be harmful to the unborn child. If you fall pregnant whilst using this formula, please discontinue immediately and inform your prescriber to explore a pregnancy-safe alternative.

#### Driving and using machines

**Tretinoin , Azelaic Acid and Tranexamic acid** are unlikely to have an effect on the ability to drive or operate machines.

#### 3. How to use your formula

- Use your 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 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 , Azelaic Acid and Tranexamic acid** can cause side effects in some people. Local side effects may occasionally occur in the form of irritation, redness, a tingling sensation, dryness or 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 and by reducing the frequency of application.

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

Reddening, peeling or scaling of the skin, which may be swollen.

Dry skin, itching, warmth or a burning sensation, rashes, pain or a stinging sensation may occur. Temporary changes (increase or decrease) in skin pigmentation may occur.

If any of these symptoms is severe, or if you get crusts, blisters, swelling or a burning sensation on the skin, stop using the lotion and consult your doctor 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. Seborrhoea, acne, skin depigmentation. Paraesthesia, discomfort, dermatitis and oedema at the application site.

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

Contact allergy has been reported with medicines containing **Tretinoin**. Cheilitis, warmth, eczema and ulceration at application site. Drug hypersensitivity, worsening of asthma.

#### Not Known (cannot be estimated from the available data)

Urticaria, rash, angioedema, dermatitis contact, eye swelling, face swelling.

## 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, 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](http://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](http://www.fda.gov/medwatch)

## 5. How to store Tretinoin, Azelaic Acid and Tranexamic acid Lotion

### KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use **Tretinoin, Azelaic Acid and Tranexamic acid** after the expiry date which is stated on the pump.

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** 0.025 g/ 0.05 g/ 0.1 g and **Azelaic Acid** 15 g and **Tranexamic acid** 5 g 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 a lotion.

Pump contains 12.5ml of lotion.

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