

# Dermatica

## Package leaflet: Information for the user Tretinoin and Azelaic 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 and Azelaic 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 and Azelaic Acid** is and what it is used for
2. What you need to know before you use **Tretinoin and Azelaic Acid**
3. How to use **Tretinoin and Azelaic Acid**
4. Possible side effects
5. How to store **Tretinoin and Azelaic Acid**
6. Contents of the pack and other information

### 1. What **Tretinoin, Azelaic 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** normalizes the growth of superficial skin cells and causes normal shedding of the cells that clog the hair follicles in areas with acne. This prevents the build-up of sebum and the formation of early acne lesions (blackheads and whiteheads).

**Azelaic Acid** is used for mild to moderate papular-pustular acne. Azelaic acid reduces hyperpigmentation of the skin caused by conditions such as melasma or post inflammatory hyperpigmentation. These active substances are more effective when combined than when used separately.

### 2. What you need to know before you use **Tretinoin and Azelaic Acid**

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

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

**IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR 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. Avoid contact of the product with eyes, eyelids, nostrils, mouth, sore, broken or inflamed skin. 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 and Azelaic Acid**.
- If you have already been treated with other local exfoliating products prior to treatment, wait until skin irritation has ceased before starting treatment. If you have been using any other skin products for acne (including ones that you bought yourself without a doctor's prescription) allow the effects of these products to wear off before starting to use **Tretinoin and Azelaic Acid**
- 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 and Azelaic 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 and Azelaic Acid**. Using **Tretinoin and Azelaic 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 and Azelaic Acid** are unlikely to have an effect on the ability to drive or operate machines.

### 3. How to use **Tretinoin and Azelaic Acid Lotion**

Apply usually once a day at night.

If skin reactions are severe, do not hesitate to seek the advice of your prescriber to adjust the frequency of application.

### Method of administration

External use only. Apply a thin layer of lotion (one to two pumps) after washing and thoroughly drying the skin. Wash hands after application.

Detailed instructions: Wash your face gently with mild soap and warm water and pat your skin dry with a towel. Dispense one to two pumps onto the fingertip. Dab the lotion on your forehead, chin, nose and both cheeks, and then gently spread it evenly over your whole face. Do not use more than the amount that has been suggested by your prescriber, or apply the product more frequently than instructed.

### Frequency of administration

Apply in the evening after washing your face thoroughly.

### If you use more **Tretinoin and Azelaic Acid**

You will not get faster or better results by using more **Tretinoin and Azelaic Acid** than recommended.

### If you forget to apply **Tretinoin and Azelaic Acid Lotion**

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

### Duration of treatment

The first signs of improvement usually appear after 4-8 weeks of treatment. Treatment should be continued for at least 3 months. This initial treatment may be followed by a maintenance treatment.

## IN ALL CASES, STRICTLY FOLLOW THE INSTRUCTIONS FROM YOUR DOCTOR.

### 4. What are the possible side effects

Like all medicines, **Tretinoin and Azelaic Acid** can cause side effects, although not everybody gets them. Local side effects may occasionally occur in the form of irritation, diffused redness (Rosacea), tingling sensation, dryness of the skin, 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.

In the first weeks of treatment, a worsening of acne may be observed, including the appearance of small white pustules. This reaction is normal, it is the accelerated elimination of microcysts that were forming in the skin.

### 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.

**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.

**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 and Azelaic Acid Lotion**

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

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

Do not store above 25°C/77°F.

Medicines should not be disposed of in wastewater or household rubbish. Ask your pharmacist what to do with unused medications. These measures will help protect the environment.

**6. Contents of the pack and other information**

**The active substances are:**

**Tretinoin** 0.05 g/ 0.1 g and **Azelaic Acid** 15 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, Sodium Citrate, Diethylhexyl Sodium Sulfosuccinate, Sodium Hydroxide.

This medicine comes in the form of a lotion.

Pump contains 12.5ml of lotion.