

BAR CODE

Package leaflet: information for the user

# Atralin 0.05% w/w Gel

(Tretinoin)

Read all of this leaflet before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## 1. What Atralin Gel is and what it is used for

Atralin Gel is a medicine used on the skin for the treatment of acne.

## 2. Before you use Atralin Gel

### Do not use Atralin Gel:

- **If you are allergic** (*hypersensitive*) to tretinoin or to any of the other ingredients of Atralin Gel. If you experience an allergic reaction the first time you use Atralin Gel, do not use it again
- **If you have had a skin cancer**, or if any other member of your family has had one
- **If you suffer from eczema** – inflamed, dry, itchy, red scaly skin

- **If you have acne rosacea** – which may cause redness of the forehead, cheeks, nose and chin
- **If you have perioral dermatitis** - irritation of the skin around the mouth.
- **Do not use Atralin Gel on children under 10 years of age**

If any of these apply to you, go back to your doctor without using Atralin Gel.

### Take special care with Atralin Gel:

- **If you have sunburn or red, itchy peeling skin**, don't use Atralin Gel on those areas until they have fully recovered.
- **You must avoid too much sun** when you are using Atralin Gel. You should also avoid other sources of UV light, such as sunbeds or ultraviolet sunlamps. If you cannot avoid sunlight (for example, if you work outdoors) protect skin treated with the gel:
  - **use a sunblock or sunscreen** with a sun protection factor (SPF) of 15 or higher
  - **wear a broad-brimmed hat.**
  - **wear clothes over treated skin** that will protect it from the sun.
- **Cold and windy weather may irritate skin** treated with Atralin Gel.
- **You can use a moisturiser during the day**, as Atralin Gel can cause a little dryness of the skin.
- **You may still use other skin products like cosmetics** during the day, but make sure that your skin is cleaned thoroughly first before applying Atralin Gel.

### Using other medicines

- **Do not use harsh (astringent) skin care products** such as skin peeling products, or products which have a strong drying effect on the skin (for example, products which contain a lot of alcohol).
- **If you have been using other skin products for acne** (including ones you may have bought yourself without a doctor's prescription) or if you have been using a skin peeling product, allow the effects of these medicines to wear off before starting to use Atralin Gel.

Consult your doctor before you apply any other medicines to your skin while you are using Atralin Gel.

## Pregnancy and breast-feeding

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

**If you are breast-feeding**, tell your doctor before treatment with Atralin Gel. You may still be able to take this medicine if your doctor considers it necessary.

## Driving and using machines

Atralin Gel is unlikely to affect your ability to drive or operate machinery.

## Important information about some of the ingredients of Atralin Gel

Atralin Gel contains butylhydroxytoluene, which may cause local skin reactions (eg contact dermatitis, an inflammation of the skin) or can cause irritation to the eyes and skin, particularly the nostrils and the skin around the mouth. It also contains parahydroxybenzoates, which may cause allergic reactions (possibly delayed).

## 3. How to use Atralin Gel

### When and how much to use

Always use Atralin Gel as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Normally your doctor will tell you to **apply Atralin Gel once a day, in the evening, after washing**, to the affected areas of the skin. All of the affected area should be treated, not just the spots.

- **Thoroughly wash and dry the area to be treated**, before applying Atralin Gel
- **Apply a small amount of Atralin Gel**, usually about the size of a pea, using clean finger tips, cotton wool or gauze.
- **Lightly cover the affected area**. Applying more Atralin Gel will not make it work more effectively. If you use too much then it may make the skin red, causing peeling and discomfort. If this happens, you should stop using Atralin Gel until these symptoms have gone away.
- **Keep away from your eyes, nostrils and mouth** when applying Atralin Gel. Wash them with water if the gel gets into them. Do not allow the gel to collect in the folds of skin around your eyes or nose.

After you have applied Atralin Gel, your skin may feel warm or sting slightly for a while. If these feelings persist, or if they get worse, consult your doctor.

Do not apply Atralin Gel to skin that is cracked and weeping or eczematous.

**When your acne has improved** (this may take more than 4 weeks) your doctor may tell you that you can apply Atralin Gel less frequently.

### Children

Do not use Atralin Gel on children under 10 years of age

### If you forget to apply Atralin Gel

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 one.

### If you swallow Atralin Gel

Atralin Gel is only for use on the skin. If any gel is swallowed, contact your doctor or nearest hospital casualty department immediately.

### If you use more Atralin Gel than you should

If you accidentally apply too much Atralin Gel, it is unlikely to do you any harm. However, always try to exactly follow the instructions for use.

## 4. Possible side effects

Like all medicines, Atralin Gel can cause side effects although not everybody gets them.

### Common effects

*(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 gel and consult your doctor immediately**.

### Uncommon effects

*(seen in between one in 1,000 and one in 100 users)*  
Irritation of the eye and swelling, blistering and crusting of the skin.

### Very rare effects

*(seen in up to one in 10,000 users)*  
Contact allergy has been reported with medicines containing tretinoin.

If any of the side effects gets severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. How to store Atralin Gel

Keep out of the reach and sight of children. Do not use Atralin Gel after the expiry date which is stated on the carton and the crimp of the tube. The expiry date refers to the last day of that month.

After first opening the gel should be stored for a maximum of three months. It is important that you record the date of opening on the container labelling.

Do not store above 25°C.

Medicines should not be disposed of in waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

## 6. Further information

### What Atralin Gel contains

The active substance is tretinoin. Atralin Gel contains 0.05% tretinoin by weight. The other ingredients are water, glycerol, soluble collagen, sodium hyaluronate, carbomer 940, butylhydroxytoluene (E321), octoxynol 9, trolamine, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), butyl parahydroxybenzoate, isobutyl parahydroxybenzoate, benzyl alcohol and phenoxyethanol.

### What Atralin Gel looks like and contents of the pack

Atralin Gel is a transparent yellow gel available in tubes of 20 g and 45 g.

### Marketing Authorisation Holder:

Beechmere Pharmaceuticals Ltd.  
Merlin Place  
Milton Road  
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### Manufacturer:

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