

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tretinoin 0.1% w/w cream

Tretinoin

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

- 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. 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 serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1 What Tretinoin cream is and what it is used for

The name of your medicine is Tretinoin cream. This is similar to Vitamin A.

Tretinoin cream is used to treat acne (also called acne vulgaris) and some other skin conditions.

It will normally take 6 to 8 weeks for your skin to improve. This means you will need to be patient.

2 Before you use Tretinoin cream

Do not use Tretinoin cream if:

- You are allergic to anything in Tretinoin cream (listed in section 6 below)
- You have ever had a tumour of the top layer of your skin, or if this condition runs in your family
- You have inflamed, red, dry and scaly skin (eczema)
- You have skin damage
- You have sunburn or skin irritation with redness, peeling or itching.
Your skin will need time to recover from this before you start using Tretinoin cream

- You have been using a skin peeling agent (which removes the top layers of your skin). Your skin will need time to recover before you start using Tretinoin cream.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Tretinoin cream

Using other skin products

- You should not use harsh (astringent) or rough (exfoliating) cosmetic products while using Tretinoin cream. This includes skin peeling agents (which remove the top layers of the skin) or products that contain alcohol, spices or lime. It also includes products which have a strong drying effect on your skin (such as some face masks, cleansers or toners)
- You should avoid getting permanent wave solutions and waxing products on skin being treated with Tretinoin cream as these can irritate your skin
- You may use ordinary make-up or moisturisers, but do not apply them at the same time as Tretinoin cream
- You can still remove hair by plucking, electrolysis or hair removal creams, but if you do this before applying Tretinoin cream it could irritate your skin.

Taking other medicines

Please tell your doctor or pharmacist if you are having or have recently had any other medicines, particularly other medicines applied to your skin. This includes medicines that you buy without a prescription or herbal medicines. This is because Tretinoin cream can affect the way some other medicines work. Also some other medicines can affect the way Tretinoin cream works. Using Tretinoin cream with other medicines for the treatment of acne may irritate your skin.

Pregnancy and breast-feeding

Do not use this medicine if you are pregnant, think you may be pregnant or might become pregnant. This is because it may affect the baby.

Talk to your doctor before using this medicine if you are pregnant or breastfeeding.

Important information about some of the ingredients of Tretinoin cream

- Tretinoin cream contains butylated hydroxytoluene (E321). This can irritate your eyes, eyelids, mouth and nostrils if it comes into contact with them
- Tretinoin cream also contains sorbic acid (E200) and stearyl alcohol. These can cause skin irritations such as contact dermatitis

3 How to use Tretinoin cream

Always use Tretinoin cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Tretinoin cream is for use on your skin.

How much to use

- Normally you start by using Tretinoin cream once or twice a day
- The frequency of applying the cream will depend on how your skin responds to the treatment
- When your skin has improved your doctor may suggest that you use it less often.
- It may take 6 to 8 weeks of treatment before your skin improves

Preparing your skin

Before applying Tretinoin cream:

- Wash your skin thoroughly with water or mild (not medicated) soap
- Dry your skin gently without rubbing
- Wait 20 to 30 minutes before applying the cream
- Do not wash treated skin more than twice a day

How and where to use

- You only need to apply a small amount
- Lightly cover the affected areas of your skin
- Use cotton wool or the tips of clean fingers
- Do not let too much of this medicine collect in folds of the skin, such as where your nose meets your face
- Do not use any Tretinoin cream on cracked or weeping skin (such as eczema)
- Do not use any Tretinoin cream on your eyes, eyelids, nostrils or mouth (mucous membranes). If it goes into any of these areas, wash them with water

Protection from the sun, cold or wind

Avoid being in the sun for too long while you are using Tretinoin cream.

Do not use sunlamps or sunbeds while you are using Tretinoin cream.

If you need to go out in the sun often:

- Use a sunscreen lotion
- Wear a broad-brimmed hat
- Wear loose clothes that will protect treated areas of your skin from the sun

While using Tretinoin cream, you may also get some skin irritation in very cold or windy weather or dry atmospheres.

If you use too much Tretinoin cream

Do not use too much of this medicine. Your skin will not improve any faster. If you use too much Tretinoin cream your skin might go red. It may also peel and feel uncomfortable. If this happens, stop using Tretinoin cream until all these symptoms have gone away.

If you forget to use Tretinoin cream

Do not worry. Do not apply twice as much cream to make up for it. Use your cream as usual when the next application is due.

If you swallow Tretinoin cream

Only use Tretinoin cream on the skin. If any is swallowed talk to a doctor or go to the nearest hospital casualty department straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Tretinoin cream can cause side effects, although not everybody gets them.

Stop using Tretinoin cream and tell your doctor straight away if you notice any of the following serious side effects. You may need medical treatment.

- Severe irritation or reddening of your skin, hives or nettle rash (urticaria) or other signs of allergy during the first few days of treatment. This only happens in a small number of people
- Blistering or scabby skin
- A burning feeling on the skin or swollen face
- Your eye or eyes become irritated

If you get any of the above, stop using this medicine and tell your doctor straight away.

Other possible side effects include:**Very common** (affects more than 1 in 10 people)

- Scaly hard skin
- Painful skin such as a stinging feeling

Common (affects fewer than 1 in 10 people)

- Headache
- Itchy, irritated or red skin
- Rash (sometimes with pimples), dermatitis
- Dry or peeling skin

Uncommon (affects fewer than 1 in 100 people)

- Changes in skin colour
- Sensitivity to light
- Feeling hot

Rare (affects fewer than 1 in 1000 people)

- Light or dark patches on your skin

It is not known whether using Tretinoin cream can increase the risk of skin tumours caused by sunlight. If any of the side effects gets serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Tretinoin cream

Keep out of the reach and sight of children. Do not store above 25°C.

Do not use Tretinoin cream after the expiry date which is stated on the tube. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 Further information

What Tretinoin cream contains

The active substance in Tretinoin cream is tretinoin. It contains 0.05% w/w.

The other ingredients are butylated hydroxytoluene (E321), alcohol ketonatus 95%, sorbic acid (E200), stearic emulsificans, alcohol cetylicus, cetiol V, sorbitolum, purified water.

What Tretinoin cream looks like and contents of the pack

Tretinoin cream is a 30 g aluminium tube containing a smooth pale yellow cream.

Manufacturer

Tretinoin cream is made in Sint Maarten by Orange Grove Pharmacy, Orange Grove Shopping Center, Cole Bay

This leaflet was last revised in September 2015.