

PACKAGE LEAFLET: INFORMATION FOR THE USER

Retin-A[®] gel 0.01%

Retin-A[®] gel 0.025%

Tretinoin

Retin-A is a registered trademark

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 you get side effects and they become 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 Retin-A is and what it is used for

The name of your medicine is Retin-A gel. It is called 'Retin-A' in this leaflet. Retin-A contains a medicine called tretinoin. This is similar to Vitamin A. Retin-A is used to treat acne (also called acne vulgaris) and is for use in people with oily skin.

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 Retin-A

Do not use Retin-A if:

- You are allergic to anything in Retin-A gel (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 a skin problem which can cause redness on the cheeks, nose, chin or forehead (acne rosacea)
- The skin around your mouth is irritated (peri-oral dermatitis)
- You have sunburn or skin irritation with redness, peeling or itching. Your skin will need time to recover from this before you start using Retin-A
- 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 Retin-A

Retin-A is not recommended for children under 10 years of age.

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 Retin-A.

Using other skin products

- You should not use harsh (astringent) or rough (exfoliating) cosmetic products while using Retin-A. This includes skin peeling agents (which remove the top layers of the skin) or products that contain alcohol. It also includes products which have a strong drying effect on your skin (such as some face masks, cleansers or toners)
- You may use ordinary make-up or moisturisers but do not apply them at the same time as Retin-A

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines. This is because Retin-A can affect the way some other medicines work. Also some other medicines can affect the way Retin-A works.

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 breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Important information about some of the ingredients of Retin-A

- Retin-A gel contains butylated hydroxytoluene (E321). This can irritate your eyes, eyelids, mouth and nostrils if it comes into contact with them

3. How to use Retin-A

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

How much to use

- Normally you start by using Retin-A once or twice a day
- 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 Retin-A:

- Wash your skin thoroughly with a mild soap
- Dry your skin without rubbing
- 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 Retin-A on cracked or weeping skin (such as eczema)

- Do not use any Retin-A 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 Retin-A. Do not use sunlamps or sunbeds while you are using Retin-A.

If you need to go out in the sun often:

- Use a sunscreen lotion with a sun protection factor (SPF) of at least 15
- Wear a broad-rimmed hat
- Wear loose cotton clothes that will protect treated areas of your skin from the sun

While using Retin-A, you may also get some skin irritation in very cold or windy weather.

If you use too much Retin-A

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

If you swallow Retin-A

Only use Retin-A 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, Retin-A can cause side effects, although not everybody gets them.

Stop using Retin-A 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, or other signs of allergy during the first few days of treatment. This only happens in a small number of people
- Blistering or crusting skin
- A burning feeling on the skin or swollen skin
- Your eye or eyes become swollen or irritated

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

The side effects listed below usually go away as treatment continues.

- Dry or peeling skin. This may go on for longer than the other side effects in this list
- Warm skin or skin which stings
- Itchy or red skin, or a skin rash
- Light or dark patches on your skin

If any of the above are severe or last for a long time, talk to your doctor or pharmacist.

It is not known whether using Retin-A can increase the risk of skin tumours caused by sunlight.

If you get side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Retin-A

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

Do not use Retin-A after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use the Retin-A if you notice that the tube seal is broken or missing.

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

The active substance in Retin-A is tretinoin. Retin-A gel contains either 0.01% or 0.025% of tretinoin.

The other ingredients are butylated hydroxytoluene (E321), hydroxypropyl cellulose (E463) and undenatured ethanol.

What Retin-A looks like and contents of the pack

Retin-A gel (both strengths) is a 60 g aluminium tube containing a clear yellow gel.

The product licence is held by:

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe,
Buckinghamshire HP12 4EG, UK

Retin-A is made by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

**For information in large print, tape, CD or Braille, telephone
0800 7318450.**

This leaflet was last approved in August 2011.