

# RETIN-A Cream & Gel

Tretinoin

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about all the RETIN-A preparations, which include:

RETIN-A 500 micrograms/g cream

RETIN-A 100 micrograms/g gel

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using RETIN-A against the benefits this medicine is expected to have for you.

If you have any concerns about using RETIN-A ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

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### What RETIN-A is used for

RETIN-A is applied to the skin for the treatment of acne.

RETIN-A contains tretinoin which is related to Vitamin A. This medicine works by causing the outer layer of the skin to grow more rapidly, which decreases the amount of the protein 'keratin' in the skin. As a result, the surface layer of the skin becomes thinner and pores are less likely to become blocked, reducing the occurrence of whiteheads, blackheads and pimples.

Your doctor may have prescribed RETIN-A for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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### Before you use RETIN-A

#### **When you must not use it**

Do not use RETIN-A if :

- you are pregnant or planning to become pregnant
- you have an allergy to RETIN-A or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.

Do not use RETIN-A if the packaging is torn or shows signs of tampering. Do not use RETIN-A beyond the expiry date (month and year) printed on the pack after the letters 'Exp', even if it has been stored properly.

#### **Before you start to use it**

You must tell your doctor if:

- you are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed
- you have sunburn or other forms of skin irritation, such as eczema. The use of RETIN-A should be delayed until the skin has fully recovered.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using RETIN-A.

Your doctor will advise you whether or not to use RETIN-A, or if you need to adjust your dose or adapt your treatment.

#### **Use with other medicines and skin treatments:**

Tell your doctor or pharmacist if you are taking any other medicines, or using any other skin treatments. This includes medicines and skin treatments you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are using any of the following:

- medicines which are known to make skin sensitive to sunlight. For example, some diuretics (fluid tablets), antibiotics and medicines for certain psychiatric conditions can cause this problem.
- other skin medications or treatments, particularly topical preparations containing peeling agents such as sulfur, resorcinol, benzoyl peroxide or salicylic acid.
- soaps, shampoos, cosmetics, perfumes and astringents such as skin-toners and after-shave lotions (especially those containing alcohol, lime and spices) which have an abrasive, drying or skin-shedding effect.

Other moisturisers and cosmetics may be used, however they should not be applied at the same time as RETIN-A. The area should be cleaned thoroughly before RETIN-A is applied.

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## Using RETIN-A

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### ***How to use RETIN-A:***

**RETIN-A cream and gel are for external use only on your skin and must not be swallowed.**

The following is the most often used dose, but your doctor may adjust the dose to suit your needs.

RETIN-A cream or gel should be applied to the skin where acne lesions appear, once a day, usually before going to bed. Wash the area to be treated using a mild, non-medicated soap. Pat the skin dry without rubbing. Allow the area to dry for at least 20-30 minutes before applying RETIN-A. Use enough RETIN-A to cover the entire affected area lightly.

It is better not to use more than the amount suggested by your doctor or pharmacist. A centimetre of RETIN-A cream or gel squeezed onto the fingertip should be enough for your whole face. Application of too much RETIN-A may irritate the skin and won't give you faster or better results.

RETIN-A should be kept away from the eyes, the mouth, angles of the nose and mucous membranes. If RETIN-A gets into these areas, wash them with water.

Following application of RETIN-A you may experience a brief stinging sensation, or a feeling of warmth on your skin. This is normal.

During the early weeks of therapy, you may notice a slight worsening of your acne. This is temporary and is related to the action of RETIN-A on non-visible, underlying acne. After 2-3 weeks you should begin to see an

improvement, but it may be 6-12 weeks before definite benefits are seen.

Continue with the treatment even if you don't see immediate improvement, and don't stop treatment at the first signs of improvement.

Some patients require less frequent applications or a lower strength of RETIN-A. Other patients may respond to more frequent applications. If you change the type of RETIN-A preparation you are using, your skin may respond differently. Your doctor may need to observe how your skin responds to the treatment, and how well it can tolerate the medication. Consult your doctor for further advice.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

### ***If you forget to use it***

- Apply RETIN-A when you remember, and then go back to using it as you would normally.
- If it is almost time for your next application, skip the one you missed.
- DO NOT apply a double amount to make up for the one you missed.

### ***If you have used too much (overdose)***

If you have applied too much RETIN-A, remove any excess applied. You may get severe skin irritation with redness, peeling, blistering and itchiness. If this happens, stop the treatment and contact your doctor.

RETIN-A should not be taken by mouth. If you or someone else has taken RETIN-A by mouth, immediately contact your doctor, or the Poisons Information Centre or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 764 766

Keep these telephone numbers handy.

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## While you are using RETIN-A

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### ***Things you must do***

- Always follow your doctor's instructions carefully.
- Avoid or minimise exposure to sunlight.
- Tell your doctor if you become pregnant while using RETIN-A.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using RETIN-A.

### ***Things you must not do***

- Do not use RETIN-A to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use more than the recommended amount.

### ***Things to be careful of***

- Avoid exposure to sunlight as much as possible while using RETIN-A. Do not use ultraviolet (UVB) sunlamps or long-wavelength ultraviolet (UVA) lamps such as in solariums. If you have sunburn, you should not use RETIN-A until you are completely recovered.
- You should be especially careful if you are exposed to sun because of your job or if you have particularly sensitive skin. When

exposure to sunlight cannot be avoided, use a good broad-spectrum sunscreen product and wear protective clothing over the treated areas.

- Other weather extremes, such as wind, cold and low humidity may also be irritating to skin treated with RETIN-A and may increase its dryness.

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## Side Effects

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All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

**Tell your doctor if you experience any of the following and they continue to worry you:**

- Dry and peeling skin
- Burning and stinging
- Irritation and inflammation
- Red, raised areas on the skin
- Rash or itching
- Change in skin colour
- Disturbance of the levels of enzymes in the liver. This usually does not cause any problems but tell your doctor you are using RETIN-A if you have a blood test, or you are suspected to have problems with your liver such as hepatitis.

**Tell your doctor immediately if you notice any of the following as you may need urgent medical care:**

- Severe or persistent irritation
- Swelling in one or both eyes

**STOP using RETIN-A and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have an allergic reaction.**

Allergy can be recognised, for instance, by skin rash, itching, shortness of breath and/or a swollen face.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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## After using RETIN-A

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### Storage

Keep RETIN-A gel and cream in a cool dry place where the temperature is below 25 degrees C.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store RETIN-A or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

### Disposal

If your doctor tells you to stop using RETIN-A gel or cream, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

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## Product Description

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### What it looks like

RETIN-A cream is a smooth, pale yellow cream, available in tubes of 20 grams.

RETIN-A gel is a smooth, clear, sticky yellow gel with an alcoholic smell, available in tubes of 30 grams.

## Ingredients

The active ingredient in RETIN-A is tretinoin.

- RETIN-A cream contains 500 micrograms of tretinoin per gram. It also contains PEG-40 stearate, stearyl alcohol, stearic acid, isopropyl myristate, butylated hydroxytoluene, sorbic acid, xanthan gum and water.
- RETIN-A Gel contains 100 micrograms of tretinoin per gram. It also contains butylated hydroxytoluene, hydroxypropylcellulose, ethanol and water.

## Sponsor

Johnson & Johnson Pacific  
45 Jones Street  
Ultimo NSW 2007  
Australia

RETIN-A is a registered trademark.

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Australian Registration Number:  
Cream - AUST R 13323  
Gel - AUST R 13324