

Package Leaflet: Information for the user

Acretin™ cream 0.025% and 0.05 % 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 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 Acretin™ is and what it is used for

The name of your medicine is Acretin™ cream It is called Acretin™ in this leaflet. Acretin™ contains a medicine called tretinoin. This is similar to Vitamin A.

Acretin™ 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 Acretin™

Do not use Acretin™ if:

- You are allergic to anything in Acretin (listed in section 6)
- You have ever had a tumor 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 Acretin™.
- 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 Acretin™.

Acretin™ 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 Acretin™.

Using other skin products

- You should not use harsh (astringent) or rough (exfoliating) cosmetic products while using Acretin™. 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 Acretin™.

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 Acretin™ can affect the way some other medicines work. Also some other medicines can affect the way Acretin™ works. Using Acretin™ 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 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 Acretin™

Acretin contains butylated hydroxytoluene. This can irritate your eyes, eyelids, mouth and nostrils if it comes into contact with them.

3. How to use Acretin™

Always use Acretin™ 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 Acretin™ once 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 Acretin™

- 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 Acretin™ on cracked or weeping skin (such as eczema).
- Do not use any Acretin™ 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 Acretin™. Do not use sunlamps or sunbeds while you are using Acretin™.

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 Acretin™ you may also get some skin irritation in very cold or windy weather.

If you use too much Acretin™

Do not use too much of this medicine. Your skin will not improve any faster.

If you use too much Acretin™ your skin might go red. It may also peel and feel uncomfortable. If this happens, stop using Acretin™ until all these symptoms have gone away.

If you swallow Acretin™

Only use Acretin™ 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,. Acretin™ can cause side effects, although not everybody gets them.

Stop using Acretin™ 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 Acretin™ 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 Acretin™

Keep out of reach of children.

Do not store above 30 °C.

Discard the tube after 3 months from opening.

Do not use Acretin™ 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 Acretin™ 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 Acretin™ is tretinoin.

Acretin™ Cream contains either 0.025% or 0.05% of tretinoin.

The other ingredients are Polyoxyl 40 stearate, Stearyl alcohol, Isopropyl myristate, Stearic acid, Butylated hydroxytoluene, Sorbic acid, Xanthan gum and Purified water.

What Acretin™ looks like and contents of the pack

Acretin™ Cream (0.025% or 0.05%) is an off-white to cream colored, homogenous smooth cream.

Acretin™ Cream (0.025% or 0.05%) comes in aluminium collapsible tube of 30gm.

Marketing Authorisation Holder and Manufacturer

Jamjoom Pharmaceuticals Co., Jeddah, Saudi Arabia.

Tel: +966-12-6081111, Fax: +966-12-6081222.

Website: www.jamjoompharma.com

To report any side effect(s):

• Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)

- o Fax: +966-11-205-7662
- o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- o Toll free phone: 8002490000
- o E-mail: npc.drug@sfd.a.gov.sa
- o Website: www.sfd.a.gov.sa/npc

• Other GCC States:

— Please contact the relevant competent authority.

This leaflet was last approved in 03/2016; Version number 04.

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed.
 - Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



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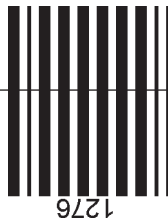
Acretin™ is a quality product manufactured by:



جمجوم فارما
Jamjoom Pharma

P.O.Box 6267 Jeddah - 21442- Saudi Arabia

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