For Topical Use Only

TRETONIOIN CREAM

PATIENT INSTRUCTIONS

Acne Treatment

IMPORTANT
Read Directions Carefully Before Using

THIS LEAFLET TELLS YOU ABOUT TRETINOIN ACNE TREATMENT AS PRESCRIBED BY YOUR PHYSICIAN. THIS PRODUCT IS TO BE USED ONLY ACCORDING TO YOUR DOCTOR’S PRESCRIPTION. THIS PRODUCT SHOULD NOT BE APPLIED TO OTHER AREAS OF THE BODY OR TO OTHER GROWTHS OR LESIONS. THE LONG-TERM SAFETY AND EFFECTIVENESS OF THIS PRODUCT IN OTHER DISORDERS HAVE NOT BEEN EVALUATED. IF YOU HAVE ANY QUESTIONS, BE SURE TO ASK YOUR DOCTOR.

WARNINGs AND PRECAUTIONs

The effects of the sun on your skin. As you know, overexposure to natural sunlight or the reflection and re-emission of sunlight by a sunlamp can cause sunburn. Overexposure to the sun over many years may cause premature aging of the skin and even skin cancer. The chance of these effects occurring will vary depending on skin type, the climate and the care taken to avoid overexposure to the sun. Therapy with tretinoin may make your skin more susceptible to sunburn and other adverse effects of the sun, so unprotected exposure to natural or artificial sunlight should be minimized.

Laboratory findings. When laboratory mice are exposed to artificial sunlight, they often develop skin tumors. These sunlight-induced tumors may appear more quickly and in greater number if the mouse is also topically treated with the active ingredient in Tretinoin Cream, tretinoin. In some studies, under different conditions, however, when mice treated with tretinoin were exposed to artificial sunlight, the incidence and rate of development of skin tumors was reduced. There is no evidence to date that tretinoin alone will cause the development of skin tumors in either laboratory animals or humans. However, investigations in this area are continuing.

Use caution in the sun. When outside, even on hazy days, areas treated with tretinoin should be protected. An effective sunscreen should be used any time you are outside (consult your physician for a recommendation of an SPF level which will provide you with the necessary degree of protection). For extended sun exposure, protective clothing, like a hat, should be worn. Do not use artificial sunlamps while you are using tretinoin. If you do become sunburned, stop your therapy with tretinoin until your skin has recovered.

Avoid excessive exposure to wind or cold. Extremes of climate tend to dry or burn normal skin. Skin treated with tretinoin may be more vulnerable to these extremes. Your physician can recommend protective measures for your acne treatment under such conditions.

Possible problems. The skin of certain sensitive individuals may become excessively red, swollen, blistered or crusted. If you are experiencing severe or persistent irritation, discontinue the use of tretinoin and consult your physician.

There have been reports that, in some patients, areas treated with tretinoin developed a temporary increase or decrease in the amount of skin pigment (color) present. The pigment in these areas returned to normal either when the skin was allowed to adjust to tretinoin or therapy was discontinued.

Use other medication only on your physician’s advice. Only your physician knows which other medications may be helpful during treatment and will recommend them to you if necessary. Follow your physician’s instructions carefully. In addition, you should avoid preparations that may dry or irritate your skin. These preparations may include certain astringents, toiletries containing alcohol, spices or lime, or certain medicated soaps, shampoos and hair permanent solutions. Do not allow anyone else to use this medication.

If you are pregnant, think you are pregnant or are nursing an infant: No studies have been conducted in humans to establish the safety of tretinoin in pregnant women. If you are pregnant, think you are pregnant, or are nursing a baby, consult your physician before using this medication.

AND WHILE YOU’RE ON TRETINOIN THERAPY
Use a mild, non-medicated soap. Avoid frequent washings and harsh scrubbing. Acne is not caused by dirt, so no matter how hard you scrub, you can’t wash it away. Washing too frequently or scrubbing too roughly may at times actually make your acne worse. Wash your skin gently with a mild, bland soap. Two or three times a day should be sufficient. Pat dry with a towel. Let the face dry 20 to 30 minutes before applying tretinoin. Remember, excessive irritation such as scratching, too much washing, use of other medications not suggested by your physician, etc., may worsen your acne.

HOW TO USE TRETINOIN
To get the best results with tretinoin therapy, it is necessary to use it properly. Forget about the instructions given for other products and the advice of friends. Just stick to the special plan your doctor has laid out for you and be patient. Remember, when tretinoin is used properly, many users see improvement by 12 weeks. Again, follow instructions—be patient—don’t start and stop therapy on your own—If you have questions, ask your doctor.
To help you use the medication correctly, keep these simple instructions in mind.

- Apply tretinoin once daily before bedtime, or as directed by your physician. Your physician may advise, especially if your skin is sensitive, that you start your therapy by applying tretinoin every other night. First, wash with a mild soap and dry your skin gently. WAIT 20 to 30 MINUTES BEFORE APPLYING MEDICATION; it is important for skin to be completely dry in order to minimize possible irritation.

- It is better not to use more than the amount suggested by your physician or to apply more frequently than instructed. Too much may irritate the skin, waste medication and won’t give faster or better results.

- Keep the medication away from the corners of the nose, mouth, eyes and open wounds. Spread away from these areas when applying.

- Cream: Squeeze about a half inch or less of medication onto the fingertip. While that should be enough for your whole face, after you have some experience with the medication you may find you need slightly more or less to do the job. The medication should become invisible almost immediately. If it is still visible, you are using too much. Cover the affected area lightly with Tretinoin Cream by first dabbing it on your forehead, chin and both cheeks, then spreading it over the entire affected area. Smooth gently into the skin.

- It is recommended that you apply a moisturizer on the fingertip. While that should be enough for your whole face, after you have some experience with the medication you may find you need slightly more or less.

- Apply tretinoin once daily, before retiring, to the skin where acne lesions appear, using enough to cover the entire affected area lightly.

- There may be some discomfort or peeling during the early days of treatment. Some patients also notice that their skin begins to take on a blush.

- These reactions do not happen to everyone. If they do, it is just your skin adjusting to tretinoin and this usually subsides within two to four weeks. These reactions can usually be minimized by following instructions carefully. Should the effects become excessively troublesome, consult your doctor.

- By THREE TO SIX WEEKS, some patients notice an appearance of new blemishes (papules and pustules). At this stage it is important to continue using tretinoin.

- If tretinoin is going to have a beneficial effect for you, you should notice a continued improvement in your appearance after 6 to 12 weeks of therapy. Don’t be discouraged if you see no immediate improvement. Don’t stop treatment at the first signs of improvement.

- Once your acne is under control you should continue regular application of tretinoin until your physician instructs otherwise.

**IF YOU HAVE QUESTIONS**

All questions of a medical nature should be taken up with your doctor.

**Manufactured for:**
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**Adverse Reactions:**

- Redness, peeling, or discomfort may occur. Oral ingestion may cause vomiting.

- In cases where it has been necessary to temporarily discontinue therapy or to reduce the frequency of application, therapy may be resumed or frequency of therapy increased.

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