

Targretin® (bexarotene) 1% gel

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Patient's Instructions for Use (For Topical Use Only)

To help you get the full benefits from this medicine, you should read this leaflet carefully and ask your doctor to explain anything you do not understand.

What are the most important things I should know about Targretin® gel?

Do not use Targretin® gel if you are pregnant or if you plan to become pregnant.

- Targretin® gel may harm your fetus (unborn baby). You should contact your doctor immediately if you believe or suspect you are pregnant while you are using Targretin® gel and until one month after you stop using Targretin® gel.
- If you are capable of becoming pregnant, you must have a pregnancy test, within one week before you start Targretin® gel therapy and monthly while you are using Targretin® gel, confirming you are not pregnant.
- You must use effective contraception (birth control) continuously starting one month before beginning treatment with Targretin® gel until one month after you stop using Targretin® gel. It is recommended that two reliable forms of contraception be used together.
- If you are male and your partner is pregnant or capable of becoming pregnant, you should discuss with your doctor the precautions you should take.

What is Targretin® gel?

Targretin (tar-GRET-in) gel contains bexarotene (beks-AIR-oh-teen). Targretin® gel belongs to a class of medicines known as retinoids.

What are the uses for Targretin® gel?

This medicine is used to treat the skin problems arising from a disease called cutaneous T-cell lymphoma, or CTCL. Your health care provider has prescribed Targretin® for the topical treatment of the cutaneous T-cell lymphoma (CTCL), or mycosis fungoides (MF), lesions (sometimes referred to as patches or plaques) on your skin. Your doctor must instruct you on the proper use of Targretin® gel. The following instructions will help you successfully begin and continue your treatment.

Do not use Targretin® gel if you are allergic to this medicine.

Do not use Targretin® gel if you are pregnant or believe you may be pregnant.

If you have any of the following conditions, make sure you have discussed them with your doctor before you start to take this medicine.

- If you are breast feeding.
- If you are allergic to retinoid medications (for example: Accutane® [isotretinoin], Soriatane® [acitretin], Tegison® [etretinate], Vesinoid® [tretinoin]).

When should you be extra careful while using Targretin® gel?

- Because vitamin A in large doses may cause some side effects which are similar to those seen in patients applying Targretin® gel, do not take more than the recommended daily dietary allowance of vitamin A (4000 to 5000 International Units). If you take vitamins, check the label to see how much vitamin A they contain. If you are not sure, ask your doctor or pharmacist.
- Your skin may become more sensitive to sunlight while using this medicine. Minimize exposure to sunlight and do not use a sunlamp.

WARNINGS

For external use only.

DO NOT apply the gel on or near mucosal surfaces of the body such as eyes, nostrils, mouth, lips, vagina, tip of the penis, rectum, or anus.

DO NOT use insect repellents containing DEET (*N,N*-diethyl-*m*-toluamide) or other products containing DEET while using Targretin® gel.

Keep out of reach of children.

Product contains alcohol and should be kept away from open flame.

DO NOT use Targretin® gel if you are pregnant or breastfeeding. Speak to your health care provider if you have any questions or need more information.

HOW TO APPLY

Apply Targretin® gel to your CTCL lesions using a clean washed finger. Place a **generous coating** of gel over the entire surface of each lesion. You should not apply gel to the healthy skin around the lesion. The extra effort you take in carefully applying the gel only to the area of the CTCL lesion will help to lessen

any irritation or redness that may occur. Proper application should leave some gel visible on the surface of the lesion when you are finished with the application.

Immediately following application, wipe the finger(s) you have used to apply the gel with a disposable tissue and wash your hands using soap and water.

Allow five (5) to ten (10) minutes for the gel to dry before covering a treated area with clothing.

A mild non-deodorant soap is recommended when bathing or showering. If you apply Targretin® gel after your shower or bath, you should wait 20 minutes before application.

WHEN TO APPLY

Targretin® gel should be applied at an initial frequency of once every other day for the first week. The frequency of application should then be increased as tolerated at weekly intervals to once daily, then twice daily, then three times daily, and finally four times daily. Your health care provider may instruct you to apply Targretin® gel at a different frequency.

YOU SHOULD AVOID...

You should avoid applying Targretin® gel to areas of healthy skin around a CTCL lesion. Exposure of healthy skin to Targretin® gel may cause unnecessary irritation or redness.

You should avoid showering, bathing, or swimming until at least three (3) hours after any application, if possible.

You should avoid covering the CTCL lesions treated with Targretin® gel with any bandage or material other than loose clothing.

You should avoid prolonged exposure of the treated area to sunlight or other ultraviolet (UV) light (such as tanning lamps).

You should avoid the use of other topical products on your treated CTCL lesions.

You should avoid scratching the treated areas.

WHAT SIDE EFFECTS DOES TARGRETIN® GEL HAVE?

While using Targretin® gel, you may experience some local effects such as redness, itching, burning, irritation, and scaling at the area of application. In clinical trials, the majority of these effects were mild or moderate, but some patients did experience more severe rash, itching, irritation, and inflammation. A few patients discontinued treatment due to these types of effects. Should these or other effects become troublesome to you, consult your health care provider. He or she can provide information on how to manage these effects.

All medications have side effects. You should call your physician regarding any questions or concerns you may have when using Targretin® gel.

HOW QUICKLY CAN I EXPECT TARGRETIN® GEL TO WORK?

Be patient. Targretin® gel takes time to work. In clinical trials, some patients began to respond as early as 4 weeks, but most patients did not experience their best response until 48 to 62 weeks of treatment. Do not stop treatment at the first sign of improvement. Continue to use Targretin® gel as instructed by your health care provider.

OTHER INFORMATION

The opening of the Targretin® gel tube is covered by a metal safety seal. If this seal has been punctured or is not visible when you first open the package, DO NOT USE this tube and promptly return the product to your pharmacy or place of purchase.

To open, use the pointed portion of the cap to puncture the metal safety seal.

Always use the cap to close the tube tightly after each use.

Store at room temperature. Keep away from heat or flame.

The gel should not be used after the expiration date printed on the tube.

Keep this medicine out of the reach and sight of children.

IF YOU HAVE QUESTIONS....

If you have questions about your treatment, talk with your health care provider.

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