Tazarotene Cream, 0.1%

IMPORTANT INFORMATION: Tazarotene cream may be used on skin sites that do not use tazarotene creams in your eyes, mouth, or vagina.

What is the most important information I should know about tazarotene cream?

Tazarotene cream may cause birth defects if used during pregnancy.

- Women must not be pregnant when they start using tazarotene cream or become pregnant during treatment with tazarotene cream.
- For females who are able to get pregnant:
  - You should avoid using tazarotene cream for at least 4 weeks before you start trying to become pregnant.
  - You should avoid using tazarotene cream if you become pregnant while using it.

What should I do if I use tazarotene cream by mistake?

- If you use tazarotene cream by mistake, wash your hands immediately and rinse the cream off your skin with water.
- If you use more than the recommended amount of tazarotene cream, call your healthcare provider or poison control center for instructions.

What are the possible side effects of tazarotene cream?

- Possible side effects of tazarotene cream may include:
  - Numbness, tingling, or itching
  - Redness, swelling, or irritation
  - Pain, burning, or skin ulcers
- If you experience any of these side effects, stop using tazarotene cream and call your healthcare provider.

How do I store tazarotene cream?

- Store tazarotene cream at room temperature away from moisture and heat.
- Keep tazarotene cream out of the reach of children.
- Do not use tazarotene cream if it has expired or if it appears to be contaminated.

What should I know about tazarotene cream and other medications?

- Tazarotene cream may interact with other medications.
- Consult your healthcare provider before using any new medications or supplements.
- Do not stop using any medications or supplements without consulting your healthcare provider.

What should I do if I experience an allergic reaction to tazarotene cream?

- If you experience an allergic reaction to tazarotene cream, stop using it immediately and call your healthcare provider for instructions.
- Do not use tazarotene cream again after an allergic reaction has occurred.

What should I do if I miss a dose of tazarotene cream?

- If you miss a dose of tazarotene cream, take it as soon as you remember. Do not double the dose.

What is the maximum amount of tazarotene cream I should use in 1 day?

- The maximum amount of tazarotene cream you should use in 1 day is 30 grams.

What should I do if I have questions about tazarotene cream?

- If you have questions about tazarotene cream, contact your healthcare provider or pharmacist.
- They can provide you with more information about the use and effects of tazarotene cream.

What should I do if I experience side effects from tazarotene cream?

- If you experience side effects from tazarotene cream, contact your healthcare provider.
- They can provide you with instructions on how to manage your side effects.

What should I do if I miss a dose of tazarotene cream?

- If you miss a dose of tazarotene cream, take it as soon as you remember. Do not double the dose.
What should I avoid while using tazarotene cream?

- Avoid sunlight, including sunlamps, during treatment with tazarotene. Tazarotene cream can make you more sensitive to the sun, so avoid direct sunlight. You could get a severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.
- Talk to your doctor if you get a sunburn during treatment with tazarotene cream. If you get a sunburn, do not use tazarotene cream until your skin is healed.
- Avoid using cosmetics or topical medicines that may make your skin more sensitive to sunlight or make your skin dry.

What are the possible side effects of tazarotene cream?

- Skin irritation. Tazarotene cream may cause increased skin irritation. Tell your doctor if you develop itching, burning, redness, or peeling during treatment with tazarotene cream. Your doctor may tell you to temporarily stop using tazarotene cream until your skin heals or tell you to use tazarotene cream less often. If you develop skin irritation, also avoid dry or cold weather may be more irritating to your skin while you are using tazarotene cream.
- Sensitivity to sunlight. See "What should I avoid while using tazarotene cream?" The most common side effects of tazarotene cream include peeling, redness, burning, and dry skin. Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the side effects possible with tazarotene cream. For more information, ask your pharmacist or chemist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store tazarotene cream?

- Store tazarotene cream at 77°F (25°C).
- Keep tazarotene cream and all medicines out of reach of children.

General information about the safe and effective use of tazarotene cream.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use tazarotene cream for a condition for which it was not prescribed. Do not give tazarotene cream to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about tazarotene cream that is written for health professionals.

What are the ingredients of tazarotene cream?

Active ingredients: tazarotene
Inactive ingredients: carbonic copolymer type E, carboxy homopolymer type E, witepsol disodium, mineral oil, purified water, sodium hydroxide (to adjust pH), sodium lauryl sulfate, sorbitan monoleate.
Manufactured by Taro Pharmaceuticals U.S.A., Inc., Westbury, NY 11590
Distributed by Taro Pharmaceuticals U.S.A., Inc., Westbury, NY 11590
Issued: October 2013
PA-1598-2-461

This Patient Information has been approved by the U.S. Food and Drug Administration.