PATIENT INFORMATION VTAMA® (Vee-TAM-uh) (tapinarof) cream, for topical use

Important information: VTAMA cream is for use on the skin (topical use) only. Do not use VTAMA cream in your eyes, mouth, or vagina.

What is VTAMA cream?

VTAMA cream is a prescription medicine used on the skin (topical) to treat:

- plaque psoriasis in adults.
- atopic dermatitis in adults and children 2 years of age and older.

It is not known if VTAMA cream is safe and effective for the topical treatment of plaque psoriasis in children. It is not known if VTAMA cream is safe and effective for the topical treatment of atopic dermatitis in children under 2 years of age.

Before using VTAMA cream, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if VTAMA cream will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VTAMA cream passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with VTAMA cream.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use VTAMA cream?

- Use VTAMA cream exactly as your healthcare provider tells you to use it.
- Apply a thin layer of VTAMA cream only to the affected skin areas 1 time a day. Avoid applying VTAMA cream to unaffected areas of your skin.
- Wash your hands after applying VTAMA cream unless you are using it to treat your hands.
- If someone else applies VTAMA cream for you, they should wash their hands after application.

What are the possible side effects of VTAMA cream?

The most common side effects of VTAMA cream in people treated for plaque psoriasis include:

- red raised bumps around the hair pores (folliculitis)
- pain or swelling in the nose and throat (nasopharyngitis)
- skin rash or irritation including itching and redness, peeling, burning, or stinging

The most common side effects of VTAMA cream in people treated for atopic dermatitis include:

- upper and lower respiratory tract infections
- red raised bumps around the hair pores (folliculitis)
- headache
- asthma

vomiting

flu

ear infection

headache

- pain in extremity
- stomach-area (abdominal) pain

VTAMA cream can also cause skin reactions at the treatment site. Tell your healthcare provider if you have itching, irritation, pain, redness, burning or changes in skin color at the treatment site.

These are not all the possible side effects of VTAMA cream.

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 VTAMA cream?

- Store VTAMA cream at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze VTAMA cream.
- Protect VTAMA cream from exposure to excessive heat.

Keep VTAMA cream and all medicines out of the reach of children.

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

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

What are the ingredients in VTAMA cream?

Active ingredient: tapinarof

Inactive ingredients: benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, edetate disodium, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

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For more information, go to www.VTAMA.com or call 1-844-674-3200.

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

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