INDICATIONS AND Usage

RHOFADE cream is an alpha, adrenergic agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

• Alpha-adrenergic agonists as a class may impact blood pressure. Advise patients with cardiovascular disease to inform the physician if signs and symptoms of potential cardiovascular insufficiency develop.

• Do not use if the ocular surface is known or suspected to be infected.

OVERDOSAGE

There are no available data on RHOFADE cream use in pregnant women to inform a drug-associated risk. See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 1%) are application site dermatitis, worsening inflammatory lesions of rosacea, application site pruritus, application site erythema, and application site pain. (5.1)

To report SUSPECTED ADVERSE REACTIONS, contact EPI Health, LLC at 1-800-494-4668 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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RHOFADE® (oxymetazoline hydrochloride) cream, 1%, is a white to off-white cream. The product is available in a laminated tube and an aerosol pump polypropylene bottle in the following packaging configurations, each with a child-resistant closure:

- NDC 71403-003-30 30 gram tube
- NDC 71403-003-45 45 gram tube
- NDC 71403-003-60 60 gram tube
- NDC 71403-003-35 30 gram pump
- NDC 71403-003-65 45 gram pump

Storage: Store at 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Important Administration Instructions

Advise patients of the following:
- RHOFADE cream is for topical use only.
- RHOFADE cream pumps require priming before initial use and discard product from the first three pumps.
- Do not apply RHOFADE cream to irritated skin or open wounds.
- Avoid contact with the eyes and lips.
- Wash hands immediately after application.
- Keep RHOFADE cream out of reach of children.

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Patient Information

including prescription and over-the-counter medicines, skin products, vitamins, and herbal supplements. Using RHOFADE cream with certain other medicines may affect each other and can cause serious side effects.

How should I use RHOFADE cream?

- See the detailed Instructions for Use that comes with your RHOFADE cream tube or pump for information about how to apply RHOFADE cream correctly.
- Use RHOFADE cream exactly as your healthcare provider tells you. Do not use more RHOFADE cream than prescribed.
- RHOFADE cream is for use on your skin only. Do not use RHOFADE cream in your eyes, mouth, or vagina.
- Avoid contact with your eyes and lips.
- Do not apply RHOFADE cream to irritated skin or open wounds.

What are the possible side effects of RHOFADE cream?

The most common side effects of RHOFADE cream include application site reactions of:
- skin reactions (dermatitis)
- worsening of rosacea pimples
- itching
- redness
- pain

These are not all the possible side effects of RHOFADE 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 RHOFADE cream?

- Store RHOFADE cream at room temperature between 68°F to 77°F (20°C to 25°C). Keep RHOFADE cream and all medicines out of the reach of children.

General information about the safe and effective use of RHOFADE cream

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use RHOFADE cream for a condition for which it was not prescribed. Do not give RHOFADE 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 RHOFADE cream that is written for health professionals.