

16 HOW SUPPLIED/STORAGE AND HANDLING

RHOFADE® (oxymetazoline hydrochloride) cream, 1%, is a white to off-white cream. The product is available in a laminated tube and an airless 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	60 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.

Manufactured for EPI Health, LLC, Charleston, SC 29403, U.S.A. by DPT Laboratories, Ltd, San Antonio, TX 78215

RHOFADE and its design are registered trademarks of EPI Health, LLC

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Patented. U.S. Patent Numbers: U.S. 7,812,049; U.S. 8,420,688; U.S. 8,815,929; U.S. 8,883,838; U.S. 9,974,773 and U.S. 10335391. Made in the U.S.A.

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<p style="text-align: center;">PATIENT INFORMATION RHOFADE® (roe' fayd) (oxymetazoline hydrochloride) cream</p>
<p>Important: RHOFADE cream is for skin (topical) use on the face only. Do not use RHOFADE cream in your eyes, mouth, or vagina. Keep RHOFADE cream out of the reach of children. Get medical help right away if you, a child, or anyone else swallows RHOFADE cream.</p>
<p>What is RHOFADE cream? RHOFADE cream is a prescription medicine used on the skin (topical) to treat facial redness due to rosacea that does not go away (persistent) in adults. It is not known if RHOFADE cream is safe and effective in children under 18 years of age.</p>
<p>Before you use RHOFADE cream, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none">• have heart, blood vessel, or blood pressure problems. Call your healthcare provider or get medical help if these conditions worsen.• have problems with blood circulation or have had a stroke• have Sjögren's Syndrome• have scleroderma• have Raynaud's phenomenon• have thromboangiitis obliterans• have narrow-angle glaucoma. Call your healthcare provider or get medical help if your glaucoma worsens.• have irritated skin or open sores on the face• are pregnant or plan to become pregnant. It is not known if RHOFADE cream will harm your unborn baby.• are breastfeeding. It is not known if RHOFADE cream passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use RHOFADE cream.
<p>Tell your healthcare provider about all the medicines you take, 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.</p>
<p>How should I use RHOFADE cream?</p> <ul style="list-style-type: none">• 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 lips and eyes.• Do not apply RHOFADE cream to irritated skin or open wounds.
<p>What are the possible side effects of RHOFADE cream? The most common side effects of RHOFADE cream include application site reactions of:</p> <ul style="list-style-type: none">• skin reactions (dermatitis)• worsening of rosacea pimples• itching• redness• pain <p>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.</p>
<p>How should I store RHOFADE cream?</p> <ul style="list-style-type: none">• Store RHOFADE cream at room temperature between 68°F to 77°F (20°C to 25°C). <p>Keep RHOFADE cream and all medicines out of the reach of children.</p>
<p>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.</p>

What are the ingredients in RHOFADE cream?

Active ingredient: oxymetazoline hydrochloride

Inactive ingredients: sodium citrate dihydrate, citric acid anhydrous, disodium edetate dihydrate, butylated hydroxytoluene, anhydrous lanolin, medium chain triglycerides, diisopropyl adipate, oleyl alcohol, polyethylene glycol 300, PEG-6 stearate, glycol stearate, PEG-32 stearate, cetostearyl alcohol, ceteareth-6, stearyl alcohol, ceteareth-25, methylparaben, propylparaben, phenoxyethanol, and purified water

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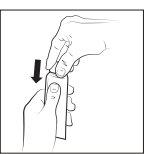


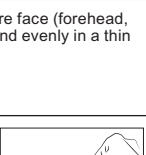
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INSTRUCTIONS FOR USE RHOFADE® (roe' fayd) (oxymetazoline hydrochloride) cream Tube	
<p>Important:</p> <ul style="list-style-type: none">• RHOFADE cream is for skin (topical) use on the face only. Do not use RHOFADE cream in your eyes, mouth, or vagina.• Keep RHOFADE cream out of the reach of children.• Get medical help right away if you, a child, or anyone else swallows RHOFADE cream.	
Read and follow the steps below so that you use your tube of RHOFADE cream correctly:	
<p>Step 1: Open the tube of RHOFADE cream by gently pressing down on the child-resistant cap and twisting it counterclockwise until the cap is removed. Do not squeeze the tube while opening or closing.</p> <p>Note: When the cap is removed, the tube is not child-resistant.</p>	
<p>Step 2: To apply RHOFADE cream to your face, squeeze a pea-sized amount of RHOFADE cream from the tube onto your fingertip.</p>	
<p>Step 3: Apply the pea-sized amount of RHOFADE cream to cover your entire face (forehead, nose, each cheek, and chin) 1 time each day. Spread the cream smoothly and evenly in a thin layer over your face.</p> <ul style="list-style-type: none">• Avoid contact with your eyes and lips.• Do not apply cream to irritated skin or open wounds.	
<p>Step 4: To close your RHOFADE cream tube, place the cap back on the tube. Press down on the child-resistant cap and twist clockwise until it stops. The tube is child-resistant again.</p>	
<p>Step 5: Wash your hands right away after applying RHOFADE cream.</p>	
<p>How do I store RHOFADE cream?</p> <ul style="list-style-type: none">• Store RHOFADE cream at room temperature between 68°F to 77°F (20°C to 25°C). <p>Keep RHOFADE cream and all medicines out of the reach of children.</p>	

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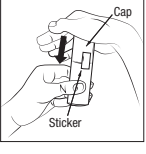
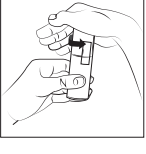
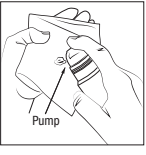
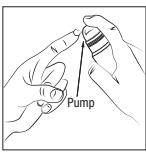
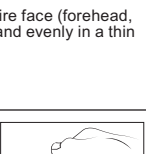
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INSTRUCTIONS FOR USE RHOFADE® (roe' fayd) (oxymetazoline hydrochloride) cream Pump
<p>Important:</p> <ul style="list-style-type: none">• RHOFADE cream is for skin (topical) use on the face only. Do not use RHOFADE cream in your eyes, mouth, or vagina.• Keep RHOFADE cream out of the reach of children.• Get medical help right away if you, a child, or anyone else swallows RHOFADE cream.

Read and follow the steps below so that you use your RHOFADE cream pump correctly:

<p>Step 1: Open the RHOFADE cream pump by pushing down on the child resistant cap and twisting it counterclockwise until the cap is removed. The clear sticker will break when opening for the first time.</p> <p>Note: When the cap is removed, the pump is not child-resistant.</p>	
<p>Prime your RHOFADE cream pump before the first use only. Hold the pump upright and press down several times until the cream is dispensed onto a tissue. Pump 3 more times onto the tissue and throw away (discard) the tissue.</p> <p>Your pump is now ready to use.</p>	
<p>Step 2: To apply RHOFADE cream to your face, press down on the pump one time to dispense a pea-sized amount of RHOFADE cream onto your fingertip.</p>	
<p>Step 3: Apply the pea-sized amount of RHOFADE cream to cover your entire face (forehead, nose, each cheek, and chin) 1 time each day. Spread the cream smoothly and evenly in a thin layer over your face.</p> <ul style="list-style-type: none">• Avoid contact with your eyes and lips.• Do not apply RHOFADE cream to irritated skin or open wounds.	
<p>Step 4: To close your RHOFADE cream pump, place the cap back on the pump. Push down on the child-resistant cap and turn the cap clockwise until it stops. The pump is child-resistant again.</p>	
<p>Step 5: Wash your hands right away after applying RHOFADE cream.</p>	
<p>How do I store RHOFADE cream?</p> <ul style="list-style-type: none">• Store RHOFADE cream at room temperature between 68°F to 77°F (20°C to 25°C). <p>Keep RHOFADE cream and all medicines out of the reach of children.</p>	

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