

Brimonidine (MIRVASO) Topical Gel 0.33%

Criteria for Use

October 2015

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vawww.pbm.va.gov> for further information.

Exclusion Criteria If the answer to ANY item below is met, then the patient should NOT receive brimonidine topical gel.

- Patients at risk for serious harm from vascular insufficiency, including those with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, thrombangiitis obliterans, scleroderma or Sjögren's syndrome.
- Patients at risk for serious harm from decrease in blood pressure, such as those with severe or unstable or uncontrolled cardiovascular disease.
- Hypersensitivity to brimonidine tartrate, phenoxyethanol (preservative) or other gel ingredients.

Inclusion Criteria The answers to ALL of the following must be fulfilled in order to meet criteria.

- Adult 18 years and older with a diagnosis of facial rosacea
 - Moderate to severe, persistent (nontransient) facial erythema of rosacea (i.e., erythematotelangiectatic [ET] rosacea)
 - Inadequate response, intolerance or contraindication to nonpharmacologic approaches for rosacea (i.e., avoidance of triggers of flushing, proper use of sun protection, and use of skin care products for sensitive skin)
 - Not more than two facial inflammatory lesions of rosacea
- OR**
- If patient has 3 or more facial inflammatory lesions of rosacea (i.e., papulopustular rosacea) in addition to ET rosacea, there must be documentation of an inadequate response (i.e., unsatisfactory improvement in persistent / nontransient erythema), intolerance or contraindication to a 4-week regimen of the following:
 - ___ Topical metronidazole (0.75% or 1% cream, gel or lotion) or topical azelaic acid (15% gel or 20% cream)
- AND**
- ___ Oral doxycycline (20 to 100 mg twice daily), minocycline (50 to 100 mg twice daily) or tetracycline (250 to 500 mg twice daily)
- Received / receiving VA care or consultation and the initial prescription for brimonidine topical gel from a dermatologist or other provider locally designated to prescribe brimonidine topical gel.

Dosage and Administration

Refer to Product Information.

Apply a pea-size amount once daily to each of the five areas of a clean and dry face: central forehead, chin, nose, each cheek. Apply smoothly and evenly as a thin layer across the entire face, avoiding the eyes and lips. Do not apply to irritated skin or open wounds. Wash hands immediately after applying the medication.

Not for oral, ophthalmic or intravaginal use.

Monitoring

- If possible, high-quality photos should be taken before starting brimonidine therapy to make an objective assessment of effectiveness.

Issues for Consideration

- **FDA Indication and Usage:** Brimonidine topical gel 0.33% is an alpha adrenergic agonist indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.
- **Warnings and Precautions**
 - *Serious Adverse Effects Following Ingestion of Brimonidine Topical Gel.* After accidentally ingesting brimonidine gel, two young children experienced lethargy, respiratory distress with apneic episodes requiring intubation, sinus bradycardia, confusion, psychomotor hyperactivity and diaphoresis and required hospitalization overnight.
 - *Worsening of Erythema and Flushing.* Some patients discontinued brimonidine gel because of erythema or flushing. These adverse effects seemed to resolve after discontinuation of brimonidine gel. Erythema may return hours after application of brimonidine gel. Some subjects in clinical trials reported return of erythema that was worse than that at baseline. Some patients reported intermittent flushing, with onsets varying from 30 minutes to several hours after application of brimonidine gel.

- **Drug Interactions**

- *Antihypertensives / Cardiac Glycosides.* Use caution. Alpha-2 agonists may reduce blood pressure
- *CNS Depressants.* Consider potential for additive or potentiating effect with CNS depressants (e.g., alcohol, anesthetics, barbiturates, opioids, sedatives).
- *Monoamine Oxidase Inhibitors.* Use caution. MAOIs may theoretically impair brimonidine metabolism and potentially result in increased systemic adverse effects such as hypotension.

- **Pregnancy Category B.** Use brimonidine gel during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers.** There is a potential for serious adverse effects from brimonidine if it is excreted in human breast milk and ingested by nursing infants. Brimonidine is excreted in animal breast milk and it is unknown whether it is excreted in human breast milk. Using patient-centered discussions, help the patient decide whether to discontinue nursing or discontinue brimonidine gel.
- **KEEP BRIMONIDINE GEL OUT OF REACH OF CHILDREN.** Accidental ingestion of brimonidine gel by two young children resulted in serious adverse effects.
- **Geriatric Use.** There is insufficient data to determine whether people aged 65 and over respond differently from younger people.

Initial Prescription Limits and Renewal Criteria

- Initial prescriptions should be limited to one 30-gram tube without refill.
 - Prescriptions may be renewed if there is documentation that the patient experienced a clinically meaningful benefit after 2 weeks of treatment.
 - If the medication is effective and tolerated, subsequent prescriptions may be written for larger quantities and have refills.
 - Brimonidine topical gel therapy should be discontinued if there is no clinically meaningful benefit.
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