



scored either “moderate” or “severe” on both scales. The primary efficacy endpoint in both pivotal trials was 2-grade Composite Success, defined as the proportion of subjects with a 2-grade improvement on both CEA and PSA measured at hours 3, 6, 9, and 12 on Day 29. Table 2 presents the efficacy results. In addition to Day 29, efficacy was evaluated on Day 15 and Day 1, and the results are presented in Figures 1 and 2 for Studies 1 and 2, respectively.

Table 2: Summary of 2-grade Composite Success on Day 29

Success	Study 1		Study 2	
	MIRVASO Topical Gel (N=129)	Vehicle Gel (N=131)	MIRVASO Topical Gel (N=148)	Vehicle Gel (N=145)
Hour 3	31%	11%	25%	9%
Hour 6	30%	10%	25%	9%
Hour 9	26%	10%	18%	11%
Hour 12	23%	9%	22%	10%

2-grade Composite Success: 2-grade improvement on CEA and 2-grade improvement on PSA.

Figure 1: 2-grade Composite Success by Hour and Day for Study 1

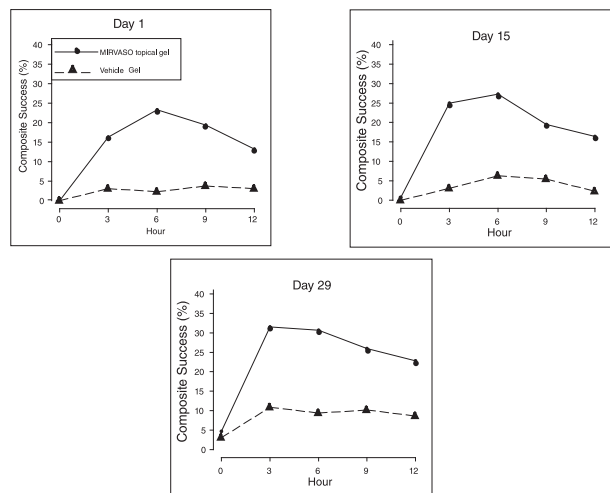
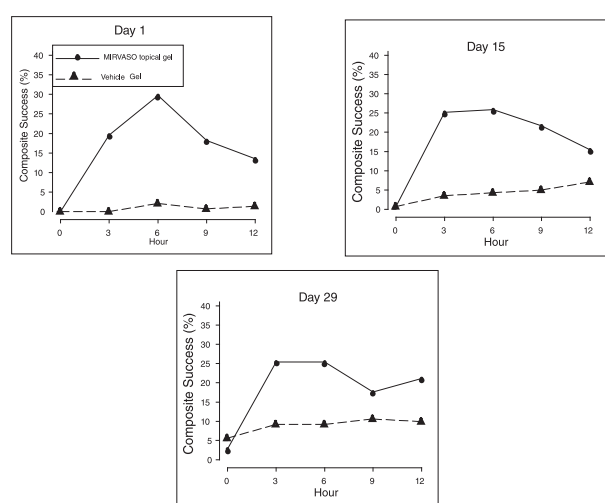


Figure 2: 2-grade Composite Success by Hour and Day for Study 2



#### 16 HOW SUPPLIED/STORAGE AND HANDLING

MIRVASO (brimonidine) topical gel, 0.33% is a white to light yellow opaque gel, supplied in a laminated tube or pump with a child resistant cap in the following sizes:

30 gram tube NDC 0299-5980-30

30 gram pump NDC 0299-5980-35

45 gram tube NDC 0299-5980-45

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature].

#### 17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information and Instructions for Use)

Patients using MIRVASO topical gel should receive the following information and instructions:

- This medication is to be used as directed by the physician.
- It is for external use only.
- MIRVASO topical gel should not be applied to irritated skin or open wounds.
- Avoid contact with the eyes and lips.
- Patients should wash their hands immediately after applying the medication.
- Some patients using MIRVASO topical gel may experience erythema, flushing or excessive whitening.
- Patients should report any adverse reactions to their physician.
- Keep out of reach of children

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#### Instructions for Use MIRVASO (Mer-VAY-soe) (brimonidine) topical gel Pump

**Important:** MIRVASO® topical gel is for use on the face only. Do not use MIRVASO topical gel in your eyes, mouth, or vagina.

**Keep MIRVASO topical gel out of the reach of children.**

**If anyone, especially a child, accidentally swallows MIRVASO topical gel, they may have serious side effects and need to be treated in a hospital. Get medical help right away if you, a child, or anyone else swallows MIRVASO topical gel and has any of these symptoms:**

- lack of energy, trouble breathing or stops breathing, a slow heart beat, confusion, sweating, restlessness, muscle spasms, or twitching.

Read and follow the steps below so that you use your MIRVASO topical gel correctly:

1. Push the cap down and turn it counter-clockwise until the cap can be removed. See Figures A and B. The clear sticker will break when opening for the first time.

**Note:** when the cap is removed, the pump is not child-resistant.

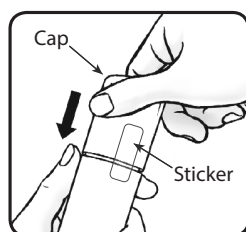


Figure A



Figure B



Figure C

Before the first use, prime the pump by pressing down several times until the medicine is dispensed onto your fingertip.

2. To apply MIRVASO topical gel to your face, dispense a pea-sized amount of MIRVASO topical gel from the pump onto your fingertip. See Figure C.
3. Apply a pea-sized amount of MIRVASO topical gel onto each of the five areas of your face (forehead, chin, nose, each cheek) 1 time each day. You will use a total of 5 pea-sized amounts of MIRVASO topical gel. Spread the gel

#### PATIENT INFORMATION

##### MIRVASO (Mer-VAY-soe) (brimonidine) topical gel

**Important information:** MIRVASO® topical gel is for use on the face only. Do not use MIRVASO topical gel in your eyes, mouth, or vagina.

**Keep MIRVASO topical gel out of the reach of children.**

**If anyone, especially a child, accidentally swallows MIRVASO topical gel, they may have serious side effects and need to be treated in a hospital. Get medical help right away if you, a child, or anyone else swallows MIRVASO topical gel and has any of these symptoms:**

- lack of energy, trouble breathing or stops breathing, a slow heart beat, confusion, sweating, restlessness, muscle spasms, or twitching.

**What is MIRVASO topical gel?**

MIRVASO topical gel is a prescription medicine that is used on your skin (topical) to treat facial redness due to rosacea that does not go away (persistent) in adults who are 18 years of age or older.

It is not known if MIRVASO topical gel is safe and effective in children.

**Who should not use MIRVASO topical gel?**

**Do not use MIRVASO topical gel if you have had a serious allergic reaction to any of the ingredients in MIRVASO topical gel.** See the end of this Patient Information leaflet for a list of ingredients in MIRVASO topical gel. **See “What are the possible side effects of MIRVASO topical gel?”**

**What should I tell my doctor before using MIRVASO topical gel?**

**Before using MIRVASO topical gel, tell your doctor about all of your medical conditions including if you:**

- have depression
- have heart or blood vessel problems
- have dizziness or blood pressure problems
- have problems with blood circulation or have had a stroke
- have dry mouth or Sjögren’s Syndrome
- have skin tightening or scleroderma
- have Raynaud’s phenomenon
- have irritated skin or open sores
- plan to have any laser procedures
- are pregnant or plan to become pregnant. It is not known if MIRVASO topical gel will harm your unborn baby.
- are breastfeeding. It is not known if MIRVASO topical gel passes into your breast milk. You and your doctor should decide if you will use MIRVASO topical gel or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, skin products, vitamins, and herbal supplements. Using MIRVASO topical gel with certain other medicines may affect each other and can cause serious side effects.

**How should I use MIRVASO topical gel?**

See the detailed Instructions for Use that comes with your MIRVASO topical gel tube or pump for information about how to use MIRVASO topical gel correctly.

- **Use MIRVASO topical gel exactly as your doctor tells you.** Do not use more MIRVASO topical gel than prescribed. Call your doctor if you are not sure.
- You should not apply MIRVASO topical gel to irritated skin or open wounds.
- MIRVASO topical gel is for use on your skin only. Do not use MIRVASO topical gel in your eyes, mouth, or vagina. Avoid contact with your lips and eyes.

**What are the possible side effects of MIRVASO topical gel?**

**MIRVASO topical gel may cause serious side effects, including:**

- **See “Important information” at the beginning of this Patient Information leaflet.**
- **Problems with blood circulation.** People who use MIRVASO topical gel can have problems with blood circulation, including a slow heart rate, low blood pressure, and dizziness. These problems may sometimes be serious and lead to hospitalization. See “What should I tell my doctor before using MIRVASO topical gel?”
- **Serious allergic (hypersensitivity) reactions** have happened in people who use MIRVASO topical gel. Stop using MIRVASO topical gel and go to the nearest hospital emergency room right away if you have any of the following signs and symptoms of a serious allergic reaction including:
  - swelling of your face, lips, tongue, or throat
  - hives
  - trouble breathing

**The most common side effects of MIRVASO topical gel include:**

- redness
- flushing
- burning sensation of the skin
- skin reactions (contact dermatitis).

Skin redness is common after applying MIRVASO topical gel, and may be worse than before you applied it. You may also develop redness on areas of your face that were not affected by rosacea, as well as on your neck and chest.

Skin flushing is common and may happen off and on after applying MIRVASO topical gel. In some cases, the flushing may be new, may happen more often, or you may have increased redness with flushing.

Pale colored skin or very white skin (excessive whitening) can happen at or outside the treated area.

Tell your doctor if you get skin redness, flushing, and pale colored skin that is uncomfortable for you.

These are not all the possible side effects of MIRVASO topical gel.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of MIRVASO topical gel**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or doctor for information about MIRVASO topical gel that is written for health professionals.

Do not use MIRVASO topical gel for a condition for which it was not prescribed. Do not give MIRVASO topical gel to other people, even if they have the same symptoms that you have. It may harm them.

**What are the ingredients in MIRVASO topical gel?**

Active ingredient: brimonidine

Inactive ingredients: carbomer homopolymer type B, glycerin, methylparaben, phenoxyethanol, propylene glycol, purified water, sodium hydroxide, titanium dioxide.

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smoothly and evenly in a thin layer over your face. Avoid contact with your eyes and lips. Do not apply MIRVASO topical gel to irritated skin or open wounds.

4. To close your MIRVASO topical gel pump, place the cap back on the pump. Push down and turn the cap to the right (clockwise) until it stops. The pump is child-resistant again. See Figure D.

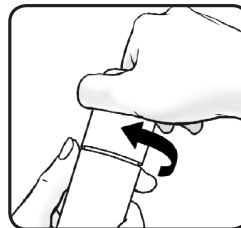


Figure D

5. Wash your hands right away after applying MIRVASO topical gel.

**How should I store MIRVASO topical gel?**

- Store MIRVASO topical gel at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep MIRVASO topical gel and all medicines out of the reach of children.**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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