

MIRVASO[®] Gel

Brimonidine 3.3mg/g

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **MIRVASO**. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using **MIRVASO** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What MIRVASO is used for

MIRVASO contains the active ingredient brimonidine tartrate that belongs to a group of substances known as alpha₂-adrenergic receptor agonists.

MIRVASO is used for treating skin of the face affected by redness due to rosacea in adult patients.

When applied to the skin, **MIRVASO** gel passes through the skin and acts specifically on the blood vessels of the face to decrease the redness of rosacea.

Ask your doctor if you have any questions about why MIRVASO has been prescribed for you.

Your doctor may have prescribed it for another reason.

MIRVASO is not addictive.

MIRVASO is available only with a doctor's prescription.

Before you use MIRVASO

When you must not use it

Do not use **MIRVASO**:

- for any child or adolescents under 18 years of age
- if you are breast-feeding
- if you are taking medicines for depression called monoamine oxidase inhibitors (eg. Nardil, Parnate) or tricyclic antidepressants (such as imipramine) or tetracyclic antidepressants (such as maprotiline, mianserin or mirtazapine).
- if you have an allergy to any medicine containing brimonidine tartrate
- if you have an allergy to any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives of the skin
- redness of skin

In case of discomfort and symptoms such as heat, itchiness or rash in the medicated or surrounding area, discontinue treatment with MIRVASO.

Do not use **MIRVASO after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- kidney problems
- liver problems

- depression
- circulatory problems
- decreased blood flow of the brain or the heart
- decreased blood flow of the hands, feet or skin
- blood pressure disorders
- Sjögren's syndrome (a chronic autoimmune disease in which a person's white blood cells attack their moisture-producing glands)

Tell your doctor if you have allergies to any other medicines, preservatives, foods or dyes.

MIRVASO contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed), and propylene glycol which may cause skin irritation.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

MIRVASO should not be used on broken or irritated skin or on/close to the mucosal areas such as:

- eyes or eyelids
- mouth
- lips
- membranes of the inner nose
- or vagina

If **MIRVASO** comes into contact with these areas, the area should be rinsed immediately with plenty of water.

Mirvaso should not be used as a lubricant or toothpaste

If you have not told your doctor about any of the above, tell him/her before you start using **MIRVASO.**

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some substances or medicines and **MIRVASO** may interfere with each

other. These include:

- some antidepressant medicines called tricyclic and tetracyclic antidepressants (eg. amitriptyline or Endep and maprotiline, mianserin or mirtazapine) or monoamine oxidase inhibitors (MAOIs, eg. Nardil, Parnate) as they could result in dangerously low blood pressure
- anaesthetic or sedative medicines, opiates or daily consumption of alcohol
- some medicines for psychosis (eg. chlorpromazine or Largactil) or for hyperactivity (eg. methylphenidate or Ritalin)
- cardiac glycosides (e.g. digoxin), used to treat heart problems.
- blood pressure lowering medicine such as beta-blockers or calcium channel blockers (e.g. propranolol, amlodipine).

These medicines may be affected by **MIRVASO** or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid whilst using **MIRVASO**.

How to use MIRVASO

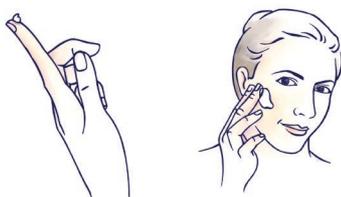
Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/tube, ask your doctor or pharmacist for help.

How to use it

MIRVASO is only intended for use on the skin in adults.

It is recommended that **MIRVASO** be applied once per day after your usual cleansing routine, and before any cosmetics or sunscreen are applied. These products may be used only after the applied **MIRVASO** has dried



Treatment should be initiated with a

smaller amount of gel (less than the maximum) for at least one week with a gradual increase in the amount of gel based on tolerability and response.

Apply a small, pea-sized amount of **MIRVASO** to each of the five areas of the face (ie. forehead, chin, nose, each cheek) avoiding the eyes, eyelids, lips, mouth, and membranes of the inner nose. The product should be applied smoothly and evenly across your face in a thin layer.

Mirvaso should be applied to the face only. Hands should be washed after applying MIRVASO.

Mirvaso should not be applied on irritated skin (including following laser therapy)

How much to use

Five small pea-sized amounts of **MIRVASO** is the maximum daily recommended dose.

Do not exceed the recommended maximum dose (1 g of gel in total weight or 5 pea-sized amounts) and frequency of application (once daily use in a thin layer).

Any increase in the daily amount applied and/or frequency of daily application of Mirvaso should be avoided, since the safety of higher daily doses or repeated daily application has not been assessed.

How to open the tube with a child-resistant cap

To avoid spillage, do not squeeze the tube while opening or closing. Push down on the cap and turn in a counter clockwise (to the left) a quarter of a turn.



How to close the tube with a child-resistant cap

Align grooves on the cap and tube. Push down and turn clockwise (to the right) a quarter turn.



How long to use it

Your doctor will tell you how long to use **MIRVASO**.

Do not use MIRVASO for longer than your doctor tells you.

If you use **MIRVASO** for longer than your doctor tells you, the chance of side effects may increase.

If you are not sure how long to use MIRVASO, talk to your doctor.

What to do if it swallowed

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764766 in New Zealand), or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have swallowed MIRVASO. Do this even if there are no signs of discomfort or poisoning, such as low blood pressure, fatigue, vomiting, somnolence, decreased or irregular heartbeats, pupil contraction, slow-low-breathing frequency, floppiness, low body temperature or convulsions. You may need urgent medical attention. Keep these telephone numbers handy.

While you are using MIRVASO

Things you must do

Tell all doctors and pharmacists who are treating you that you are using MIRVASO.

If you feel that MIRVASO is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used MIRVASO exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using MIRVASO, tell your doctor.

Things you must not do

Do not use MIRVASO to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not exceed the recommended dose and frequency of application.

Things to be careful of

MIRVASO should not be used the mucosal areas such as:

- eyes or eyelids
- mouth
- lips
- membranes of the inner nose
- or vagina.

If MIRVASO comes into contact with these areas, the area should be rinsed immediately with plenty of water.

MIRVASO should not be used as a lubricant or toothpaste.

Avoid excessive exposure to sunlight and UV lamps.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a non-comedogenic, broad spectrum, SPF 50+ sunscreen.

Ask your doctor if you are concerned about the length of time you have been using MIRVASO.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using MIRVASO.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

The more common side effects of MIRVASO include:

- skin redness
- itching of the skin
- flushing of the skin
- skin burning sensation.
- too much whitening of the application site
- worsening of rosacea

These side effects are usually mild and short-lived. Tell your doctor if you notice any of these and they worry you.

The uncommon side effects of MIRVASO include:

- skin discomfort, irritation, warmth or pain
- tingling or stinging at application site
- dry skin or rash
- dry mouth
- swelling of the eyelids
- feeling hot
- headache
- flu-like symptoms
- nasal congestion
- dizziness
- swelling of skin
- hives
- swelling of face
- upper respiratory tract infection
- acne

The rare side effects of MIRVASO include:

- low blood pressure
- heart rate decrease

Some people may get other side effects while using MIRVASO.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using MIRVASO

Storage

MIRVASO should be stored in a cool, dry place where the temperature stays below 25°C.

Do not refrigerate below 2°C.

Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres (5 feet) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MIRVASO is a white to light yellow, opaque gel. It is supplied in either: A PE/Al/PE laminated plastic tubes with a HDPE head and plastic (PP) cap containing 2 grams of gel (sample) or with a plastic (PP) child-resistant cap containing 10 or 30 grams (trade) of gel.

Or

A PE (HDPE)/Al/PE copolymer polyfoil plastic tubes with a HDPE head and PE child-resistant cap containing 2 grams (sample) or 10 or 30 grams (trade) of gel.

Or

A PE (HDPE + LLDPE)/LLDPE/Al/PE copolymer polyfoil plastic tubes with a HDPE head and PE child-resistant cap containing 2 grams (sample) or 10 or 30 grams (trade) of gel.

Not all pack sizes may be distributed in Australia.

Ingredients

Each gram of MIRVASO contains 3.3mg of brimonidine as the active ingredient.

It also contains the inactive ingredients:

- glycerol
- propylene glycol
- carbomer 934P
- phenoxyethanol
- methyl hydroxybenzoate (E218)
- titanium dioxide
- sodium hydroxide
- purified water

Sponsor/ distributor

Mirvaso is distributed in Australia by: Galderma Australia Pty Ltd
Level 18, 1 Denison Street
North Sydney NSW 2060
Ph 1800 800 765

Mirvaso is distributed in New Zealand by: Healthcare Logistics'
58 Richard Pearce Drive
Airport Oaks
Auckland
Telephone 0800 174 104

Made in France

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