

MIRVASO® 3 mg/g gel **brimonidine**



Package leaflet: Information for the patient **Mirvaso 3 mg/g gel** **brimonidine**

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Mirvaso is and what it is used for
2. What you need to know before you use Mirvaso
3. How to use Mirvaso
4. Possible side effects
5. How to store Mirvaso
6. Contents of the pack and other information

1. What Mirvaso is and what it is used for

Mirvaso contains the active substance brimonidine which belongs to a group of medicines commonly referred to as "alpha agonists". It is applied to the skin of the face to treat redness due to rosacea in adult patients.

Redness of the face due to rosacea is caused by high levels of blood flow in the facial skin, which is the result of enlargement (dilation) of the small blood vessels of the skin.

When applied, Mirvaso acts to narrow these blood vessels again which reduces the excess blood flow and redness.

2. What you need to know before you use Mirvaso

Do not use Mirvaso:

- if you are allergic to brimonidine or any of the other ingredients of this medicine (listed in section 6).
- in children below 2 years of age, as they may be at greater risk of side effects from any of the medicine absorbed through the skin.
- if you are taking certain medicines used for depression or Parkinson's disease including so-called monoamine oxidase (MAO) inhibitors (for example selegiline or moclobemide) or tricyclic antidepressants (such as imipramine) or tetracyclic antidepressants (such as maprotiline, mianserin or mirtazapin).
- Use of Mirvaso when taking these medicines may result in a fall in blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist, before using Mirvaso especially if:

- the skin of your face is irritated or has open wounds.
- you have problems with your heart or your blood circulation.
- you have depression, decreased blood flow to the brain or the heart, fall in blood pressure on standing up, decreased blood flow to the hands, feet or skin, or Sjögren's syndrome (a chronic disease in which the body's natural defence - the immune system - attacks the moisture-producing glands).
- you have kidney or liver problems or have had them in the past.
- you have had, or plan or have any laser procedure on the skin of your face.

It is important to start treatment with a small amount of gel, increase the dose gradually but do not exceed the maximum dose of 1 gram (approximately 5 pea sized amounts). See also instructions 'How to use Mirvaso'.

Do not apply Mirvaso more than once a day and do not exceed the maximum daily dose of 1 gram (approximately 5 pea sized amounts). See also instructions 'How to use Mirvaso'.

Worsening of skin redness, flushing or burning feeling of the skin:

Up to 1 in 6 patients experience the return of their redness worse than it was initially. Such worsening of redness usually develops within the first 2 weeks of treatment with Mirvaso. Generally, it resolves spontaneously after treatment is stopped. The effect should gradually disappear within a few days in most cases. Before you restart the treatment with Mirvaso, test it on a small area of the face on a day when you can stay at home. If you do not experience worsening of

redness or burning, continue with the usual treatment (see section 3). In case of worsening or unexpected redness, discontinue the treatment and contact your doctor.

If any of the above applies to you, talk to your doctor since this medicine may not be suitable for you.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 years because the safety and efficacy has not been established for this age group. This is particularly important in children under the age of 2 years (see 'Do not use Mirvaso').

Other medicines and Mirvaso

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because these medicines could affect your treatment with Mirvaso or Mirvaso could affect your treatment with these medicines.

Do not take Mirvaso with selegiline, moclobemide, imipramine, mianserin, or maprotiline, which are medicines that can be used for depression or Parkinson's disease, as this could lead to a change in the effectiveness of Mirvaso or could increase the chances for side effects such as a fall in blood pressure (see under 'Do not use Mirvaso').

Also, tell your doctor if you are taking any of the following medicines:

- medicines used for the treatment of pain, sleep disorders, or anxiety disorders.
- medicines used for the treatment of psychiatric disorders (chlorpromazine) or used for hyperactivity (methylphenidate) or used for high blood pressure (reserpine).
- medicines which act on the same body mechanism as Mirvaso (other alpha agonists, e.g. clonidine; so-called alpha blockers or alpha antagonists, e.g. prazosin, isoprenaline which are most often used for treatment of high blood pressure, slow heart rate or asthma).
- 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).

If any of the above applies to you, or if you are unsure, talk to your doctor.

Mirvaso with alcohol

Tell your doctor if you consume alcohol regularly as this could affect your treatment with this medicine.

Pregnancy and breast-feeding

The use of Mirvaso is not recommended during pregnancy. This is because its effects on your unborn baby are unknown.

You should not use this medicine during breast-feeding, as it is unknown whether this medicine passes into the breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

Mirvaso has no significant influence on the ability to drive and use machines.

Mirvaso contains

Methylparahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed). **This medicine also contains 55 mg propylene glycol (E1520)** in each gram which is equivalent to 5.5% w/w, it may cause skin irritation.

3. How to use Mirvaso

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Important: Mirvaso is intended for adults and only for use on the skin of the face. Do not use this medicine on other parts of your body, especially moist body surfaces, e.g. your eyes, mouth, nose or vagina. Do not swallow. Keep Mirvaso gel away from children.

How to use Mirvaso

Mirvaso is recommended to be applied to the face once a day only.

During the first week, start the treatment with a small amount of gel (a pea-sized amount) as explained by your doctor or nurse.

If your symptoms remain the same or improve only slightly, you may then gradually increase the amount of gel. Spread it smoothly and evenly as a very thin layer as directed by your doctor or nurse. It is important not to exceed the maximum daily dose of 1 gram (5 pea sized amounts applied to the whole face).

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You should wash your hands immediately after applying this medicine. If your symptoms worsen during treatment with Mirvaso (increased redness, or burning), stop treatment and make an appointment to see your doctor – see also section 2 under 'Warnings and precautions'. You must avoid the eyes, eyelids, lips, mouth, and the inside of the nose. Should any gel get onto these areas, wash them immediately with plenty of water. If you experience worsening of redness or burning you should stop using Mirvaso and contact your doctor if needed. Do not apply any other skin medicines or cosmetics immediately before the daily application of Mirvaso. You should use these products only after the applied Mirvaso has dried.

Pay attention when opening the tube for the first time, not to spill a larger quantity of gel than what is needed. If this occurs, you should discard the excess gel so as not to apply more than the recommended dose. See paragraph "How to use Mirvaso" above.

How to open the tube with a child-resistant cap

To avoid spilling, do not squeeze the tube while opening or closing. Push down on the cap and turn counter clockwise (turn to the left). Then pull the cap off.



How to close the tube with a child-resistant cap

Push down and turn clockwise (turn to the right).



If you use more Mirvaso than you should

If you use more than the maximum daily dose of 1 gram within a 24 hour period, it could lead to skin irritation or other side effects at the application site. Repeated doses within the same 24 hour period could result in side effects, such as low blood pressure, drowsiness or sleepiness. Please contact your doctor, who will advise you on what action to take.

If anyone, especially a child, accidentally swallows Mirvaso, they may have serious side effects and need to be treated in a hospital.

Contact your doctor immediately or go to a hospital emergency department right away if you, a child, or anyone else swallows this medicine and has any of these symptoms: feeling dizzy from low blood pressure, vomiting, tiredness or drowsiness, decreased or irregular heartbeats, small pupils (constricted pupils), difficult or slow breathing, floppiness, low body temperature and convulsions (fits). Take the medicine pack with you, so the doctor knows what was swallowed.

If you forget to use Mirvaso

Mirvaso works on a daily basis, starting with the first day of treatment. If you miss a daily dose, your redness will not be reduced for that day. Do not use a double dose to make up for a forgotten dose and continue your treatment as prescribed.

If you stop using Mirvaso

A potential consequence of stopping the treatment before finishing the course of treatment is the disease to come back to its initial state. Please contact your doctor before stopping your treatment, so that he could advise a replacement treatment as appropriate.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop uncommon side effects of severe skin irritation or inflammation, skin rash, skin pain or discomfort, dry skin, warm skin sensation, tingling or sensation of pins and needles or swelling of the face or common side effects like worsening of rosacea, discontinue the treatment and talk to your doctor since this medicine may not be suitable for you. In some cases, symptoms may extend beyond the treatment area. See also section 2 under 'Warnings and precautions'.

If you develop contact allergy (e.g. allergic reaction, rash) or rare angioedema (a serious allergic reaction see rarely usually with swelling of the face, mouth or tongue), stop using Mirvaso and seek prompt medical advice. Mirvaso may also cause the following other side effects:

Common side effects (may affect up to 1 in 10 people):

- flushing
- excessive whitening (pallor) where the gel is applied
- skin redness, burning feeling of the skin or itching

Uncommon side effects (may affect up to 1 in 100 people):

- acne
- dry mouth
- feeling cold in hands and feet
- feeling hot
- headache
- nasal congestion
- swelling of the eyelid
- urticaria
- dizziness

Rare side effects (may affect up to 1 in 1000 people):

- hypotension (blood pressure decreased)
- heart rate decrease (slow heart rate, known as bradycardia).

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Mirvaso

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

Store below 30°C and do not freeze.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Mirvaso contains

- The active substance is brimonidine. One gram of gel contains 3.3 mg of brimonidine, equivalent to 5 mg of brimonidine tartrate.
- The other ingredients are carbomer, methylparahydroxybenzoate (E218), phenoxyethanol, glycerol, titanium dioxide, propylene glycol (E1520), sodium hydroxide, purified water. See end of section 2 for information on methylparahydroxybenzoate and propylene glycol.

What Mirvaso looks like and contents of the pack

Mirvaso is a white to light yellow, opaque gel. It is supplied in tubes containing 2, 10 or 30 grams of gel or in airless pump system containing 30 g of gel.

Pack size of 1 tube.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Detailed information on this medicine is available on the

European Medicines Agency web site: <http://www.ema.europa.eu>.

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