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EPAR summary for the public

Mirvaso

brimonidine

This is a summary of the European public assessment report (EPAR) for Mirvaso. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Mirvaso.

For practical information about using Mirvaso, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mirvaso and what is it used for?

Mirvaso is a medicine that contains the active substance brimonidine tartrate. It is used to treat the facial erythema (redness of the skin of the face) in adults with rosacea, a long-term skin condition that often causes flushing and redness.

How is Mirvaso used?

Mirvaso is available as a gel (3 mg/g) and can only be obtained with a prescription. Mirvaso should only be applied to the skin of the face. Small amounts of gel (about pea size) are applied to the skin of the forehead, chin, nose and cheeks once a day as a thin layer. The areas should be left to dry out before applying other creams or cosmetics. For further information, see the package leaflet.

How does Mirvaso work?

Rosacea is a skin condition affecting mainly the face. Symptoms include episodes of redness that have been linked to the widening of small blood vessels in the skin of the face, which increases the blood flow to the area.

The active substance in Mirvaso, brimonidine tartrate, works by attaching to receptors called alpha$_2$-adrenergic receptors on the cells of blood vessels of the skin and activating them. This causes these blood vessels to narrow, which reduces the blood flow to the face, thus decreasing the redness.

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What benefits of Mirvaso have been shown in studies?

Mirvaso has been evaluated in two main studies involving a total of 553 patients with moderate or severe facial redness caused by rosacea. Both studies compared Mirvaso with placebo (a dummy gel) over four weeks of treatment. The main measure of effectiveness was the percentage of patients who achieved a marked reduction of facial redness at different time points (3, 6, 9 and 12 hours) on days 1, 15 and 29 after the start of the treatment.

Both studies showed that Mirvaso applied once a day was more effective than placebo at reducing the facial redness in these patients.

- In the first study, on day 1 the percentage or patients who had reduction of facial redness 3 hours after application was 16.3% (21 out of 129) for Mirvaso compared with 3.1% (4 out of 131) for placebo. Effects were maintained for 12 hours after application although the effects started to wear off after 6 hours. On day 29, 31.5% (40 out of 127) patients had reduction of facial redness 3 hours after application with Mirvaso compared with a response of 10.9% (14 out of 128) for placebo.

- In the second study, on day 1 the percentage or patients who had reduction of facial redness 3 hours after application was 19.6% (29 out of 148 patients) for Mirvaso compared with 0 % (none out of 145 patients) for placebo. Effects were also maintained for 12 hours after application and started to wear off after 6 hours. On day 29, 25.4% (36 out of 142) of patients had reduction of facial redness 3 hours after application with Mirvaso compared with a response of 9.2 % (13 out of 142) for placebo.

What are the risks associated with Mirvaso?

The most common side effects with Mirvaso (which may affect more than 1 in 100 people), which are usually mild to moderate in severity, are erythema (redness), pruritus (itching), flushing and a burning sensation of the skin. For the full list of side effects reported with Mirvaso, see the package leaflet.

Mirvaso must not be used in children below 2 years of age or in patients receiving other medicines such as monoamine oxidase (MAO) inhibitors or certain antidepressants. Mirvaso should not be used in children or adolescents aged from 2 to 18 years. For the full list of restrictions, see the package leaflet.

Why is Mirvaso approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Mirvaso's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP concluded that Mirvaso improves the facial redness in patients with rosacea. Regarding safety, the CHMP acknowledged that the safety profile is acceptable since most of the adverse events reported occur locally (on the skin) and are similar to those commonly observed with other rosacea medicines applied to the skin.

What measures are being taken to ensure the safe and effective use of Mirvaso?

A risk management plan has been developed to ensure that Mirvaso is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Mirvaso, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Mirvaso

The European Commission granted a marketing authorisation valid throughout the European Union for Mirvaso on 21 February 2014.

The full EPAR and risk management plan summary for Mirvaso can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Mirvaso, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2014.