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EPAR summary for the public

Ventavis

iloprost

This is a summary of the European public assessment report (EPAR) for Ventavis. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ventavis.

What is Ventavis?

Ventavis is a medicine that contains the active substance iloprost. It is available as a solution for inhalation using a nebuliser.

What is Ventavis used for?

Ventavis is used for the treatment of adult patients with class III primary pulmonary hypertension to improve exercise capacity (the ability to carry out physical activity) and symptoms. Pulmonary hypertension is abnormally high blood pressure in the arteries of the lungs. 'Primary' means that there are no other diseases of the heart or lungs causing the high blood pressure, and the 'class' reflects the severity of the symptoms caused by the disease: 'class III' involves marked limitation of physical activity.

The medicine can only be obtained with a prescription.

How is Ventavis used?

Treatment with Ventavis should be started and monitored by a doctor experienced in the treatment of pulmonary hypertension. Ventavis is given by inhalation using a nebuliser (a special machine that changes the solution into an aerosol that the patient can breathe in).

The recommended dose is 2.5 or 5 micrograms. Patients should start with the low dose of 2.5 micrograms for the first inhalation, and if the first dose is well tolerated, the second and

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consecutive doses should be 5 micrograms. The dose should be reduced to 2.5 micrograms again if the patient cannot tolerate the higher dose. The medicine must be given using a type of nebuliser known as a 'dosimetric' nebuliser, which stops automatically when the correct dose has been delivered. It is given six to nine times a day. If the patient has liver or kidney problems, the time between doses should be at least three to four hours.

How does Ventavis work?

Pulmonary hypertension is a debilitating disease where there is severe constriction (narrowing) of the blood vessels of the lungs that causes high blood pressure in the vessels taking blood from the right side of the heart to the lungs. Ventavis is an inhaled formulation of iloprost, a substance that is very similar to prostacyclin, a naturally occurring molecule that causes blood vessels to dilate (expand). By dilating these blood vessels, the blood pressure is reduced and symptoms are improved.

How has Ventavis been studied?

Ventavis has been compared with placebo (a dummy treatment) in one study involving 203 adults with stable class III or IV pulmonary hypertension that was either primary or caused by another condition. The main measure of effectiveness was the number of patients who had responded to treatment after 12 weeks. A 'response' was defined as a combination of a 10% improvement in exercise capacity (measured by looking at how far the patient could walk in six minutes) and an improvement of the patient's condition (the severity of the disease going down by at least one class), without a worsening of pulmonary hypertension or death.

What benefit has Ventavis shown during the studies?

Ventavis was significantly more effective than placebo: 17% of the patients taking Ventavis responded to treatment (17 out of 101), compared with 5% of the patients taking placebo (5 out of 102). However, when looking at different groups of patients in this study, a benefit of Ventavis that would be relevant for patients was only shown in patients with class III primary pulmonary hypertension.

What is the risk associated with Ventavis?

The most common side effects with Ventavis (seen in more than 1 patient in 10) are headache, vasodilation (blood vessels becoming wider causing flushing or reddening of the face), bleeding episodes, chest pain and discomfort, peripheral oedema (swelling, especially of the ankles and feet), nausea (feeling sick), pain in the jaw and contraction of the jaw muscles, and cough. For the full list of all side effects reported with Ventavis, see the package leaflet.

Ventavis must not be used in patients who are at risk of bleeding, who have certain heart problems, who have recently had a stroke, or whose pulmonary hypertension is caused by a blocked or narrow vein. For the full list of restrictions, see the package leaflet.

Why has Ventavis been approved?

The CHMP decided that Ventavis's benefits are greater than its risks and recommended that it be given marketing authorisation.

Ventavis was originally authorised under 'exceptional circumstances' because, as the disease is rare, limited information was available at the time of approval. As the company had supplied the additional information requested at the time of authorisation, the 'exceptional circumstances' ended on 26 August 2013.

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

A risk management plan has been developed to ensure that Ventavis 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 Ventavis, 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 Ventavis

The European Commission granted a marketing authorisation valid throughout the European Union for Ventavis on 16 September 2003.

The full EPAR for Ventavis 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 Ventavis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2014.