EMA/513094/2016
EMEA/H/C/004186

EPAR summary for the public

Mysildecard

sildenafil

This is a summary of the European public assessment report (EPAR) for Mysildecard. 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 Mysildecard.

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

What is Mysildecard and what is it used for?

Mysildecard is a medicine used to treat adults and children from 1 year of age with pulmonary arterial hypertension (PAH, abnormally high blood pressure in the arteries of the lungs). In adults, it is used in patients with class II (slight limitation of physical activity) or class III (marked limitation of physical activity) PAH.

Mysildecard contains the active substance sildenafil. It is a 'generic medicine'. This means that Mysildecard is similar to a 'reference medicine' already authorised in the European Union (EU) called Revatio. For more information on generic medicines, see the question-and-answer document here.

How is Mysildecard used?

Mysildecard can only be obtained with a prescription and treatment should be started and monitored by a doctor who has experience in the treatment of PAH.

Mysildecard is available as tablets (20 mg). In adults, Mysildecard is taken at a dose of 20 mg three times a day. Lower doses of Mysildecard may be needed in patients taking some medicines that affect the way Mysildecard is broken down in the body.

In children aged one to 17, the recommended dose is 20 mg three times a day in those over 20 kg. Higher doses should not be used. In children weighing less than 20 kg the maximum recommended

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dose would be 10 mg three times a day but Mysildecard can only be used when a 20 mg dose is to be given. For lower doses, other medicines containing sildenafil should therefore be used.

How does Mysildecard work?

PAH is a debilitating disease where there is severe constriction (narrowing) of the blood vessels of the lungs. This leads to high blood pressure in the vessels taking blood from the heart to the lungs and reduces the amount of oxygen that can get into the blood in the lungs, making physical activity more difficult. The active substance in Mysildecard, sildenafil, belongs to a group of medicines called 'phosphodiesterase-type-5 (PDE5) inhibitors', which means that it blocks the PDE5 enzyme. This enzyme is found in the blood vessels of the lungs. When it is blocked, a substance called 'cyclic guanine monophosphate' (cGMP) cannot be broken down, so that it remains in the vessels where it causes relaxation and widening of the blood vessels. In patients with PAH, sildenafil widens the blood vessels of the lungs, which lowers the blood pressure and improves symptoms.

How has Mysildecard been studied?

Because the effectiveness and safety of sildenafil in PAH is already well established, studies in people have been limited to tests to determine that it is bioequivalent to another authorised sildenafil-containing tablet. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. In this case Mysildecard was not compared with the reference product Revatio, but with Viagra. This was considered acceptable since Revatio and Viagra have the same qualitative composition and are made in the same way by the same manufacturer.

What are the benefits and risks of Mysildecard?

Because Mysildecard is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Mysildecard approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Mysildecard was considered to be comparable to Revatio. Therefore, the CHMP's view was that as for Revatio the benefit of Mysildecard outweighs the identified risks. The Committee recommended that Mysildecard be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Mysildecard have been included in the summary of product characteristics and the package leaflet.

Other information about Mysildecard

The European Commission granted a marketing authorisation valid throughout the European Union for Mysildecard on 15 September 2016.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 09-2016.