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Adcirca[1] *(tadalafil)*

An overview of Adcirca and why it is authorised in the EU

What is Adcirca and what is it used for?

Adcirca is a medicine used to treat adults and children from 2 years of age with pulmonary arterial hypertension (PAH).

PAH is a disease where there is abnormally high blood pressure in the arteries of the lungs. Adcirca is used in patients with PAH class II (where the patients have slight limitation of physical activity) and PAH class III (where patients have marked limitation of physical activity).

Adcirca contains the active substance tadalafil.

How is Adcirca used?

Adcirca is available as tablets and as a liquid to be taken by mouth. Both can only be obtained with a prescription. Treatment should only be started and monitored by a doctor who has experience in the treatment of PAH.

The recommended dose for adults is 40 mg once a day. For children the dose depends on the child's weight. A lower starting dose is recommended in patients with mild or moderate kidney or liver problems. Adcirca is not recommended for patients with severe kidney or liver problems. For more information about using Adcirca, see the package leaflet or contact your healthcare provider.

How does Adcirca work?

PAH is a debilitating disease where there is severe narrowing of the blood vessels of the lungs. It causes high blood pressure in the vessels taking blood from the heart to the lungs. This pressure reduces the amount of oxygen that can get into the blood in the lungs, making physical activity more difficult.

The active substance in Adcirca, tadalafil, 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 the enzyme is blocked, a substance called 'cyclic guanosine monophosphate' (cGMP) cannot be broken down and remains in the vessels where it causes the

[1] Previously known as Tadalafil Lilly.

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relaxation and widening of the blood vessels. In patients with PAH, this lowers the blood pressure in the lungs and improves symptoms.

What benefits of Adcirca have been shown in studies?

Adcirca was more effective than placebo at improving exercise capacity based on one main study involving 406 patients with PAH, most of whom had class II or class III disease. Before treatment, these patients could walk an average of 343 metres in six minutes. After 16 weeks, this distance had increased by 26 metres more in the patients taking 40 mg Adcirca than in the patients taking placebo.

An additional study in 35 children with PAH also showed that treatment with Adcirca led to an improvement in the distance the children could walk in six minutes with Adcirca, which was consistent with that observed in adults.

What is the risk associated with Adcirca?

The most common side effects with Adcirca (seen in more than 1 patient in 10) are headache, flushing (reddening of the skin), nasopharyngitis (inflammation of the nose and throat) including a blocked or runny nose and blocked sinuses, nausea (feeling sick), dyspepsia (heartburn)including abdominal (belly) pain or discomfort, myalgia (muscle pain), back pain and pain in the extremities (arms, hands, legs and feet).

Adcirca must not be used in patients who have had an acute myocardial infarction (sudden heart attack) within the last three months, or who have severe hypotension (low blood pressure). Adcirca must not be taken with nitrates (a group of medicines used to treat angina) or medicines of the class 'guanylate cyclase stimulators' such as riociguat (another medicine to treat pulmonary hypertension). It must not be used in patients who have ever had loss of vision because of a problem called non-arteritic anterior ischaemic optic neuropathy (NAION) that affects the blood flow to the nerve in the eye.

For the full list of all side effects and restrictions with Adcirca, see the package leaflet.

Why has Adcirca been approved?

The European Medicines Agency decided that Adcirca's benefits are greater than its risks and it can be authorised for use in the EU. Studies show that Adcirca improved walking ability in adults and children, and the side effects are manageable.

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

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

As for all medicines, data on the use of Adcirca are continuously monitored. Suspected side effects reported with Adcirca are carefully evaluated and any necessary action taken to protect patients.

Other information about Adcirca

Adcirca received a marketing authorisation valid throughout the EU on 1 October 2008. This authorisation was based on the authorisation granted to Cialis in 2002 (‘informed consent’). The name of the medicine was changed to Adcirca on 21 October 2009.

Further information on Adcirca can be found on the Agency’s website: ema.europa.eu/medicines/human/EPAR/adcirca

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