EMA/174531/2025
EMEA/H/C/002737

Adempas (*riociguat*)

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

What is Adempas and what is it used for?

Adempas is a medicine used to treat pulmonary hypertension (high blood pressure in the blood vessels of the lungs). It is used in the following types of pulmonary hypertension:

- Chronic thromboembolic pulmonary hypertension (CTEPH, where the blood vessels of the lungs are blocked or narrowed with blood clots). Adempas is used to treat adults with CTEPH who cannot have surgery, or in whom CTEPH remains or returns after surgery.
- Pulmonary arterial hypertension (PAH, where the walls of the blood vessels of the lungs are thickened and the vessels become narrowed) in adults and in children above 6 years of age. In adults with PAH, Adempas can be used on its own or in combination with other medicines for PAH called endothelin receptor antagonists whereas in children it is used with endothelin receptor antagonists.

Adempas is used in patients with functional class II to III CTEPH or PAH. The 'class' reflects the seriousness of the disease: class II involves a slight limitation of physical activity while class III involves a marked limitation of physical activity.

Adempas contains the active substance riociguat.

How is Adempas used?

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

Adempas is available as tablets. For patients unable to swallow whole tablets, the tablets may be crushed and mixed with water or soft food such as apple sauce. For children weighing below 50 kg Adempas is also available as granules that can be made up into a liquid to be taken by mouth.

The usual recommended starting dose depends on the patient's bodyweight and is taken three times a day (approximately 6 to 8 hours apart) for two weeks. The dose is then increased every two weeks based on the patients' systolic blood pressure (blood pressure when the heart is contracting) until the

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

appropriate dose for the individual patient is established. Treatment with the established dose should continue unless patients experience signs and symptoms of low blood pressure, in which case the dose should be reduced.

For more information about using Adempas, see the package leaflet or contact your healthcare provider.

How does Adempas work?

CTEPH and PAH are debilitating diseases where there is severe narrowing of the blood vessels of the lungs. This causes high blood pressure in the vessels taking blood from the heart to the lungs and reduces the blood flow to the lungs. As a result, the amount of oxygen that can get into the blood in the lungs is reduced, making physical activity more difficult.

The active substance in Adempas, riociguat, stimulates an enzyme called 'soluble guanylate cyclase' in the blood vessels of the lungs, causing the blood vessels to relax and widen. This helps to lower the blood pressure in the lungs and improve symptoms of CTEPH and PAH.

What benefits of Adempas have been shown in studies?

Adempas has been shown to be effective at improving exercise capacity, measured as the distance patients with CTEPH or PAH could walk in 6 minutes:

- Adempas was compared with placebo (a dummy treatment) in one main study in 262 adults with CTEPH who could not have surgery, or in whom CTEPH remained or returned after surgery. Before treatment, the patients could walk an average of 347 metres in 6 minutes. After 16 weeks of treatment with Adempas, patients could walk an average of 46 metres further in 6 minutes than patients taking placebo.
- The medicine was also compared with placebo in another main study in 445 adults with PAH. Before treatment, the patients could walk an average of 363 metres in 6 minutes. After 12 weeks, patients treated with Adempas could walk an average of 36 metres further in 6 minutes than patients taking placebo.
- A main study also showed that Adempas can improve walking distance and other signs of heart function in children. Based on evidence from this study, the medicine is expected to work as well in children as it does in adults.

What are the risks associated with Adempas?

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

The most common side effects with Adempas (which may affect more than 1 in 10 people) include headache, dizziness, dyspepsia (heartburn), peripheral oedema (swelling, especially of the ankles and feet), nausea (feeling sick), diarrhoea and vomiting. Serious side effects include haemoptysis (coughing up blood) and pulmonary haemorrhage (bleeding in the lungs).

Adempas must not be used in patients with severely reduced liver function, with low systolic blood pressure or with pulmonary hypertension associated with idiopathic interstitial pneumonia (scarring of the lungs with unknown cause). It must also not be used during pregnancy, or together with certain other medicines used to treat heart conditions.

Why is Adempas approved?

The European Medicines Agency considered that Adempas led to significant improvements in exercise capacity in patients with CTEPH or PAH. It also noted that no other medicines have been authorised for CTEPH. Regarding safety it considered that side effects of concern, including haemoptysis and pulmonary haemorrhage, have been adequately reflected in the product information and risk management plan. The Agency therefore decided that Adempas's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Adempas

Adempas received a marketing authorisation valid throughout the European Union on 27 March 2014.

Further information on Adempas can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/adempas.

This overview was last updated in 06-2025.