



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Adempas riociguat

On 23 January 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Adempas, 0.5 mg, 1 mg, 1.5 mg, 2.0 mg and 2.5 mg, film-coated tablets intended for the treatment of chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension. The applicant for this medicinal product is Bayer Pharma AG. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Adempas is riociguat, an antihypertensive for pulmonary arterial hypertension (C02KX05). Riociguat is a stimulator of soluble guanylate cyclase (sGC), an enzyme in the cardiopulmonary system and the receptor for nitric oxide (NO). When NO binds to sGC, the enzyme catalyses synthesis of the signalling molecule cyclic guanosine monophosphate (cGMP). Intra-cellular cGMP plays an important role in regulating processes that influence vascular tone, proliferation, fibrosis, and inflammation. Riociguat sensitises sGC to endogenous NO by stabilising the NO-sGC binding and directly stimulates sGC independently of NO.

The benefits with Adempas are its ability to provide significant improvement in exercise capacity and pulmonary haemodynamics in CTEPH and PAH. The most common side effects are headaches, hypotension, gastrointestinal adverse events (AEs), dizziness and peripheral oedema. Some reported AEs are of concern considering the reported imbalance with the placebo group, e.g. haemoptysis, pulmonary haemorrhages and renal impairment.

A pharmacovigilance plan for Adempas will be implemented as part of the marketing authorisation.

The approved indication is:

“Chronic thromboembolic pulmonary hypertension (CTEPH)

Adempas is indicated for the treatment of adult patients with WHO functional class II to III with

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



- inoperable CTEPH,
- persistent or recurrent CTEPH after surgical treatment,

to improve exercise capacity (see section 5.1).

Pulmonary arterial hypertension (PAH)

Adempas, as monotherapy or in combination with endothelin receptor antagonists, is indicated for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO functional class (FC) II to III to improve exercise capacity.

Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease (see section 5.1)."

Adempas should only be prescribed by physicians experienced in the treatment of CTEPH or PAH.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Adempas and therefore recommends the granting of the marketing authorisation.