16 September 2021
EMA/CHMP/508328/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Adempas

riociguat

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Adempas. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted a new contraindication as follows:

Concomitant use with other soluble guanylate cyclase stimulators.

For information, the full contraindications for Adempas will be as follows:[2]

- Co-administration with PDE5 inhibitors (such as sildenafil, tadalafil, vardenafil) (see sections 4.2 and 4.5).
- Severe hepatic impairment (Child Pugh C).
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Pregnancy (see sections 4.4; 4.5 and 4.6).
- Co-administration with nitrates or nitric oxide donors (such as amyl nitrite) in any form including recreational drugs called 'poppers' (see section 4.5).
- **Concomitant use with other soluble guanylate cyclase stimulators.**
- Patients with systolic blood pressure < 95 mm Hg at treatment initiation.
- Patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) (see section 5.1)

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

[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
[2] **New text in bold**

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