15 September 2016
EMA/592404/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Granpidam

sildenafil

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Granpidam, intended for the treatment of pulmonary arterial hypertension. The applicant for this medicinal product is Accord Healthcare Ltd.

Granpidam will be available as 20 mg film-coated tablets. The active substance of Granpidam is sildenafil, a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) (ATC code: G04BE03). Sildenafil increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with pulmonary arterial hypertension this can lead to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilatation in the systemic circulation.

Granpidam is a generic of Revatio, which has been authorised in the EU since 28 October 2005. Studies have demonstrated the satisfactory quality of Granpidam and its bioequivalence to Viagra, a sildenafil-containing medicine with the same qualitative composition as Revatio. A question and answer document on generic medicines can be found here.

The full indication is:

"Adults

Treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.

Paediatric population

Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease".

It is proposed that Granpidam be prescribed by physicians experienced in the treatment of pulmonary arterial hypertension.

[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

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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.