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Questions and answers on Flolan and associated names (epoprostenol, 0.5 and 1.5 mg powder for solution for infusion)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 24 May 2012, the European Medicines Agency completed a review of Flolan. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Flolan in the European Union (EU).

What is Flolan?

Flolan is a medicine that contains the active substance epoprostenol. It is used to prevent blood clotting during haemodialysis (technique for removing waste products from the blood used in patients with kidney disease). Flolan is also used to treat a lung condition called 'pulmonary arterial hypertension' (high blood pressure in the lungs).

The active substance in Flolan, epoprostenol, is a natural occurring prostaglandin that works by stopping the blood from clotting. It stops the activation of the blood clotting mechanism by preventing platelets (components that help the blood to clot) from sticking together. Epoprostenol also widens the blood vessels which helps to lower the blood pressure in the lungs.

Flolan is marketed in the following EU Member States: Austria, Belgium, Czech Republic, Denmark, Estonia, France, Ireland, Italy, Luxembourg, Malta, the Netherlands, Spain, United Kingdom, as well as Norway. It is also available under the trade name Epoprostenol.

The company that markets these medicines is GlaxoSmithKline.

Why was Flolan reviewed?

Flolan is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

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Flolan was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 15 June 2011, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Flolan in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the use of the medicine, the CHMP agreed that Flolan should be used for the following:

- treatment of pulmonary arterial hypertension (PAH) (idiopathic or heritable PAH and PAH associated with connective tissue diseases) in patients with WHO functional class III-IV symptoms to improve exercise capacity;
- haemodialysis in emergency situations when the use of heparin carries a high risk of causing or exacerbating bleeding, or when heparin is otherwise contraindicated.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on the use of Flolan in the elderly and patients with reduced kidney and liver function.

4.3 Contra-indications

In harmonising the contraindications, the CHMP decided to remove three contraindications that were in the SmPCs of some EU countries: pulmonary veno-occlusive disease, hypotension and angina. The CHMP was of the view that patients with pulmonary veno-occlusive disease could benefit from treatment with Flolan and that for hypotension and angina it was more appropriate to include relevant warnings in section 4.4.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.6 (pregnancy and lactation), 4.5 (Interaction with Other Medicinal Products and Other Forms of Interaction) and 4.8 (side effects).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 8 August 2012.