Summary of Investigation Results

Epoprostenol sodium

July 17, 2024

Non-proprietary name

Epoprostenol sodium

Brand name (marketing authorization holder)

Flolan for Injection 0.5 mg, 1.5 mg (GlaxoSmithKline K.K.), and the others

Japanese market launch

0.5 mg: April 1999, 1.5 mg: July 2001

Indications

Pulmonary arterial hypertension

Summary of revisions

“Ascites” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving ascites‡ in adverse drug reactions, etc. reports in Japan* and literature reports† were evaluated. Cases for which a causal relationship between epoprostenol sodium and ascites was reasonably possible have been reported (3 cases in adverse drug reactions, etc. reports in Japan and 2 cases in literature reports§). As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

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This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Reference: Number of cases and patient mortalities involving ascites*‡ reported in Japan

A total of 6 cases have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

One instance of patient mortality has been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

*: Cases collected in the PMDA's database for adverse drug reactions, etc. reports

†: Cases retrieved by a literature search performed by the marketing authorization holder

‡: Cases of “ascites (PT)” or “haemorrhagic ascites (PT)” were retrieved as cases involving ascites. Among them, cases involving “ascites” which possibly falls under grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 were evaluated.

§: One Japanese case (Kataoka, et al.: Annals ATS.2013; 10: 726-727) and 2 overseas cases (Schoenberg, et al. : Pulmonary Circulation. 2022; 12: e12092, Ruopp, et al. : Chest. 2017; 152: A1027) were retrieved. However, the Japanese case was excluded from the number of cases reported in literature since it was the duplicate report of adverse drug reactions, etc. reports in Japan.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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