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.

Summary of investigation results

Treprostinil

May 30, 2017

Non-proprietary name

Treprostinil

Brand name (Marketing authorization holder)

Treprost for Injections 20 mg, 50 mg, 100 mg, 200 mg (Mochida Pharmaceutical Co., Ltd)

Indications

Pulmonary arterial hypertension (WHO functional classification; Class II, III and IV)

Summary of revision

“Hyperthyroidism” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of hyperthyroidism have been reported in patients treated with treprostinil in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with hyperthyroidism have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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