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

Nintedanib ethanesulfonate

Non-proprietary name

Nintedanib ethanesulfonate

Brand name (Marketing authorization holder)

Ofev Capsules 100 mg, 150 mg (Nippon Boehringer Ingelheim Co., Ltd.)

Indications

Idiopathic pulmonary fibrosis

Summary of revision

“Thrombocytopenia” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of thrombocytopenia have been reported in patients treated with nintedanib ethanesulfonate 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 three fiscal years in Japan

A total of 5 cases associated with thrombocytopenia have been reported (including 3 cases for which a causal relationship to the product could not be ruled out). Of the 5 cases, 2 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be ruled out for 1 of these patients).

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