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

January 12, 2016

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

1. “Patients with moderate to severe hepatic function disorder (Child-Pugh B and C)” should be newly added in the Important Precautions section.

Background of the revision and investigation results

The results from the clinical pharmacokinetic study conducted among patients with hepatic function disorder, which was ongoing at the time of approval, showed that blood concentration of nintedanib ethanesulfonate increased in patients with hepatic function disorder. 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 reaction and fatal cases in the last 3 fiscal years in Japan

N/A

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp