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

Revision of Precautions

Non-proprietary name

Nintedanib ethanesulfonate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following text should be added (underlined parts are revised):

Thrombocytopenia:

There have been reports of thrombocytopenia, including serious cases leading to bleeding. Patients should be carefully monitored through periodic blood tests, etc. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be adopted.

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