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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Nintedanib ethanesulfonate

March 15, 2022

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Nintedanib ethanesulfonate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Nephrotic syndrome may occur. Urine protein tests should be performed periodically during administration of this drug.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Nephrotic syndrome</u>

N/A: Not Applicable. No corresponding language is included in the current package insert.

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