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Translated by
Pharmaceuticals and Medical Devices Agency



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

Sultopride hydrochloride

Fluphenazine decanoate

March 31, 2020

Therapeutic category

Psychotropics

Non-proprietary name

Sultopride hydrochloride, fluphenazine decanoate

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Contraindications Patients with Parkinson's disease	Contraindications Patients with Parkinson's disease <u>or dementia with Lewy bodies</u>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS Patients with Parkinson's disease	2. CONTRAINDICATIONS Patients with Parkinson's disease <u>or dementia with Lewy bodies</u>

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