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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

Sertraline hydrochloride

January 10, 2024

Therapeutic category

Psychotropic agents

Non-proprietary name

Sertraline hydrochloride

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
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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
Important Precautions (N/A)	Important Precautions <u>Thrombocytopenia may occur. Blood tests should be performed during the period that this drug is administered.</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Thrombocytopenia</u>

[Reference] Summary of MID-NET® study (Evaluation of the effect of antidepressants on indices of decreased platelet count using MID-NET®)
<https://www.pmda.go.jp/files/000265893.pdf>

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

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

Revised language is underlined.

Current	Revision

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<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>(N/A)</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p><u>Thrombocytopenia may occur. Blood tests should be performed during the period that this drug is administered.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Thrombocytopenia</u></p>
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