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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

Leflunomide

May 9, 2023

Therapeutic category

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

Non-proprietary name

Leflunomide

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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
<p>Important Precautions</p> <p>Administration of this drug should be discontinued if serious adverse reactions, such as pancytopenia, oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, serious infection, or serious liver disorder occur. A drug elimination procedure should be preferably performed.</p> <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis:</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome) <u>or</u> toxic epidermal necrolysis may occur. If these symptoms occur, administration of this drug should be discontinued, and appropriate measures should be taken.</p>	<p>Important Precautions</p> <p>Administration of this drug should be discontinued if serious adverse reactions, such as pancytopenia, oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, <u>skin ulcer</u>, serious infection, or serious liver disorder occur. A drug elimination procedure should be preferably performed.</p> <p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, <u>skin ulcer</u>:</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>toxic epidermal necrolysis or skin ulcer</u> may occur. If these symptoms occur, administration of this drug should be discontinued, and appropriate measures should be taken.</p>

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. 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.

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Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis</p> <p>Administration of this drug should be discontinued. A drug elimination procedure should be preferably performed.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, <u>skin ulcer</u></p> <p>Administration of this drug should be discontinued. A drug elimination procedure should be preferably performed.</p>

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