

Published by
Ministry of Health, Labour and Welfare



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

Standardized cedar pollen extract (liquid, those for sublingual administration only)

Dermatophagoides pteronyssinus extract bulk powder/*dermatophagoides farinae* extract bulk powder

July 9, 2019

Therapeutic category

Allergic agents-miscellaneous

Non-proprietary name

Standardized cedar pollen extract (liquid), *dermatophagoides pteronyssinus* extract bulk powder/*dermatophagoides farinae* extract bulk powder

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Safety measure

Precautions should be revised in the package insert.

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>Patients should be instructed to avoid intense exercise, alcohol consumption, bathing, etc., <u>approximately 2 hours before and after taking this drug.</u></p>	<p>Important Precautions</p> <p>Patients should be instructed to avoid intense exercise, alcohol consumption, bathing, etc., <u>before and 2 hours after taking this drug, and to be alert for the onset of adverse reactions such as anaphylaxis when engaged in such activities 2 hours or more after taking this drug.</u></p>

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp