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

Cedar pollen extract powder

Dermatophagoides pteronyssinus extract/dermatophagoides farina

extract

July 9, 2019

Therapeutic category Allergic agents-miscellaneous

Non-proprietary name

())

Cedar pollen extract powder, dermatophagoides pteronyssinus extract/dermatophagoides farina extract

Safety measure Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> 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 | Important Precautions |
| Patients should be adequately instructed on the following prior to | Patients should be adequately instructed on the following prior to |
| administration of this drug: | administration of this drug: |
| Intense exercise, alcohol consumption, bathing, etc., should be | Intense exercise, alcohol consumption, bathing, etc., should be |
| avoided approximately 2 hours before and after the administration | avoided before and 2 hours after taking this drug. Patients should |
| of this drug. | be alert for the onset of adverse reactions such as anaphylaxis |
| | when engaged in such activities 2 hours or more after taking this |
| | drug. |

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