



Summary of Investigation Results

Cedartolen Japanese cedar pollen

sublingual drop 200 JAU/mL bottle and the

others, Actair house dust mite sublingual

tablets 100 units (IR) and the others,

Miticure house dust mite sublingual tablets

3,300 JAU and the others, Cedarcure

Japanese cedar pollen sublingual tablets

2,000 JAU and the others

July 9, 2019

Non-proprietary name*

- a. Standardized cedar pollen extract (liquid)
- b. Allergen extract (1) (tablet)
- c. Allergen extract (2) (tablet)
- d. Cedar pollen extract

Branded name (Marketing authorization holder)

- a. Cedartolen Japanese cedar pollen sublingual drop 200 JAU/mL bottle, 2,000 JAU/mL bottle, 2,000 JAU/mL pack (Torii Pharmaceutical Co., Ltd.)
- b. Actair house dust mite sublingual tablets 100 units (IR), 300 units (IR) (Shionogi & Co., Ltd.)

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- c. Miticure house dust mite sublingual tablets 3,300 JAU, 10,000 JAU (Torii Pharmaceutical Co., Ltd.)
- d. Cedarcure Japanese cedar pollen sublingual tablets 2,000 JAU, 5,000 JAU (Torii Pharmaceutical Co., Ltd.)

Indications

a. and d.

Cedar pollinosis (desensitization therapy)

b. and c.

Desensitization therapy against allergic rhinitis caused by mite antigens

Summary of revisions

A precaution for adverse reactions including anaphylaxis that may occur following intense exercise etc. independently of the time course after this drug is taken should be added to the current precaution that intense exercise, alcohol consumption, bathing, etc. should be avoided for approximately 2 hours before and after this drug is taken in the “Important Precautions” section.

Investigation results and background of the revision

The necessity to revise the current precaution was discussed in response to reported cases of anaphylaxis following exercise engaged in 2 hours or more after an oral sublingual immunotherapeutic agent is taken. MHLW/PMDA concluded based on the results of their investigation of the currently available evidence and in consultation with expert advisors that revision of the package insert was necessary to add a precaution that patients should be instructed to be alert to a possible onset of adverse reactions including anaphylaxis if they engaged in intense exercise etc. regardless of the length of time that elapsed since this drug is taken.



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

Number of cases reported to date involving anaphylaxis following exercise or bathing engaged in 2 hours or more after this drug was taken**:

- a. 2 (no patient mortalities)
- b. 0
- c. 2 (no patient mortalities)
- d. 0

*No established nonproprietary names are available for the drugs listed here. Names of ingredients are indicated instead.

**A causal relationship between the drug and event was not evaluated in any of these cases.