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Summary of Investigation Results

Fosravuconazole L-lysine ethanolate

February 25, 2020

Non-proprietary name

Fosravuconazole L-lysine ethanolate

Branded name (Marketing authorization holder)

Nailin Capsules 100 mg (Sato Pharmaceutical Co., Ltd.)

Indications

<Applicable microorganisms>

Dermatophyte (genus Trichophyton)

<Applicable conditions>

Nail tinea

Summary of revisions

“Erythema multiforme” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of erythema multiforme have been reported in patients treated with fosravuconazole L-lysine ethanolate in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency

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

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

A total of 8 cases involving erythema multiforme have been reported to date (including 5 cases for which a causal relationship between the drug and event could not be ruled out).

No patient mortalities have been reported to date.

(Japanese market launch: July 2018)

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).