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Summary of Investigation Results

Fingolimod hydrochloride

December 17, 2021

Non-proprietary name

Fingolimod hydrochloride

Branded name (Marketing authorization holder)

Imusera Capsules 0.5 mg (Mitsubishi Tanabe Pharma Corporation)

Gilenya Capsules 0.5 mg (Novartis Pharma K.K.)

Indications

Prevention of relapse and delay of progression of physical disability in multiple sclerosis

Summary of revisions

1. Statements concerning the following should be added to the IMPORTANT PRECAUTIONS section.
   1) Performing periodic blood tests regarding thrombocytopenia
   2) Severe exacerbation of disease after discontinuation
2. “Thrombocytopenia” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of thrombocytopenia have been reported in patients treated with fingolimod hydrochloride in Japan and overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Cases of severe exacerbation of disease after discontinuation have been reported in patients treated with fingolimod hydrochloride in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency

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

Cases involving thrombocytopenia

No cases have been reported to date.

Cases involving severe exacerbation of disease after discontinuation

A total of 20 cases have been reported to date (including 18 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

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).

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