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Summary of Investigation Results

Glatiramer acetate

November 5, 2020

Non-proprietary name

Glatiramer acetate

Branded name (Marketing authorization holder)

Copaxone S.C. Injection 20 mg Syringe (Takeda Pharmaceutical Company Limited.)

Indications

Prevention of relapse of multiple sclerosis

Summary of revisions

1. A statement concerning periodic liver function tests should be added to the Important Precautions section and the IMPORTANT PRECAUTIONS section.
2. “Hepatic impairment” should be added to the Clinically Significant Adverse Reactions section and the CLINICALLY SIGNIFICANT ADVERSE REACTIONS section.

Investigation results and background of the revision

Cases of hepatic impairment have been reported in patients treated with glatiramer acetate in Japan and overseas. 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

1 case involving hepatic impairment has been reported to date (A causal relationship between the drug and event is reasonably possible for this case.)
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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