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Summary of investigation results

Interferon beta-1b (genetical recombination)

January 10, 2017

Non-proprietary name

Interferon beta-1b (genetical recombination)

Brand name (Marketing authorization holder)

Betaferon Subcutaneous Injection. 9.6 million IU (Bayer Yakuhin, Ltd.)

Indications

Prophylaxis of multiple sclerosis relapse and suppression of progression

Summary of revision

“Thrombotic thrombocytopenic purpura (TTP) and haemolytic uraemic syndrome (HUS)” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of thrombotic thrombocytopenic purpura (TTP) and haemolytic uraemic syndrome (HUS) have been reported in patients treated with interferon beta-1b (genetical recombination) both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been revised. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with thrombotic thrombocytopenic purpura (TTP) or haemolytic uraemic syndrome (HUS) have been reported (a causal relationship to the product could not be established for both cases). No fatality has been reported.

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NOTE:

* CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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