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Revision of Precautions

Interferon beta-1a (genetical recombination)

July 7, 2015

Non-proprietary name

Interferon beta-1a (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Information on liver disorder in the Important precautions section should be revised as follows (underlined parts are revised):

> Serious liver disorder such as fulminant hepatitis may occur. Prior to starting and during administration, patients should be carefully monitored by assessing hepatic function (AST [GOT], ALT [GPT], γ-GTP, etc.) periodically (every 1 to 3 months). If any abnormalities are observed, appropriate measures such as dose reduction or cessation of the drug should be adopted. Patients who have a history of hepatic function disorder are recommended to assess their hepatic function 1 to 2 weeks after the start of administration. In addition, liver disorder may occur if this drug is used in combination with other drugs reported to cause hepatic function disorder or with alcohol; therefore, great care should be exercised when using this drug in combination. In addition, if symptoms such as nausea and vomiting, malaise, inappetence, dark urine, or yellowing of the bulbar conjunctiva occur after the administration of this drug, patients should be instructed to contact a doctor.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following text should be revised (underlined parts are revised):

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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Fulminant hepatitis, hepatitis, and hepatic function disorder:

Serious liver disorder such as fulminant hepatitis, hepatitis, or hepatic function disorder may occur. Biochemical tests, including liver function tests, should be periodically performed. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.

NOTE

・ Pen-type formula is designated to prepare a Drug Guide for Patients.

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