

Published by  
Ministry of Health, Labour and Welfare



Translated by  
Pharmaceuticals and Medical Devices Agency



---

*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Interferon beta-1b (genetical recombination)

April 4, 2022

### **Therapeutic category**

Other biological preparations

### **Non-proprietary name**

Interferon beta-1b (genetical recombination)

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>2. CONTRAINDICATIONS</p> <p><u>Pregnant women or women who may be pregnant</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>This drug <u>should not be administrated</u> to pregnant women or women who may be pregnant. Foetal deaths and spontaneous abortions have been reported as observed in an animal study (monkeys) at higher doses of this drug.</p>	<p>2. CONTRAINDICATIONS</p> <p>(deleted)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>This drug <u>should be administered</u> to pregnant women or women who may be pregnant <u>only if the potential therapeutic benefits are considered to outweigh the potential risks.</u> Foetal deaths and spontaneous abortions have been reported as observed in an animal study (monkeys) at higher doses of this drug.</p>

**Pharmaceuticals and Medical Devices Agency**

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