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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

Mecasermin

(genetical recombination)

December 3, 2019

Therapeutic category

Hormones-miscellaneous

Non-proprietary name

Mecasermin (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

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Precautions concerning Indications (N/A)</p> <p>Important Precautions <u>This drug should be administered only if the therapeutic benefits to patients are considered to outweigh the associated risk because mammary gland tumour including adenocarcinoma has been reported to occur as observed in an animal study that administered this drug to SD rats for 53 weeks.</u></p>	<p><u>Precautions concerning Indications</u></p> <p><u>This drug should be administered only if the therapeutic benefits to patients are considered to outweigh the associated risks taking account the following:</u></p> <ul style="list-style-type: none"> <u>· Although causality is unclear, benign and malignant tumors have been reported to occur in patients during or after the completion of treatment with mecasermin in Japan and overseas.</u> <u>· Mammary gland tumour including adenocarcinoma has been reported to occur as observed in an animal study that administered this drug to SD rats for 53 weeks.</u> <p>Important Precautions (deleted)</p>

N/A: Not Applicable, because the section is not included in the current package insert.

(Reference) Jo,W.,et al.:Clin.Pediatr.Endocrinol. 2013;22(2):33-38

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