

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

Insulin human (genetical recombination) (vial preparations)
Insulin aspart (genetical recombination) (vial preparations without description for continuous subcutaneous insulin infusion (CSII) therapy in the Dosage and Administration section)
Insulin glargine (genetical recombination) (vial preparations)

May 19, 2020

Therapeutic category

Hormones-miscellaneous

Non-proprietary name

Insulin human (genetical recombination), insulin aspart (genetical recombination), insulin glargine (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>Important Precautions (N/A)</p>	<p>Important Precautions</p> <p><u>By repeated injection into the same spot, cutaneous amyloidosis or lipodystrophy may occur in the injection site. Injection sites should be examined periodically and patients should be instructed as follows:</u></p> <ul style="list-style-type: none"> <u>· This drug should be injected at least 2 to 3 cm apart from the previous injection site.</u> <u>· If any masses and indurations that formed in the injection site are noted, injection into the affected area should be avoided.</u> <p><u>Injection of this drug into areas where cutaneous amyloidosis or lipodystrophy developed may impede the absorption of this drug and result in poor glycemic control. If poor glycemic control is recognized, the injection site should be examined for mass or induration and appropriate measures should be taken such as changing the injection site as well as dose adjustment. Cases of hypoglycemia have been reported that occurred after the injection site was changed, and insulin preparation was injected into an unaffected area in doses excessively increased in association with the poor glycemic control.</u></p>

Pharmaceuticals and Medical Devices Agency

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

	<p><u>Incorrect doses of insulin may be injected by confusing the number of units of insulin per milliliter of liquid (insulin units) with the volume of the liquid (mL). Syringes dedicated to the insulin vials that are calibrated in insulin units or other measurement units should be used to formulate or administer an injection liquid.</u></p>
--	--

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>By repeated injection into the same spot, cutaneous amyloidosis or lipodystrophy may occur in the injection site. Injection sites should be examined periodically and patients should be instructed as follows:</u></p> <ul style="list-style-type: none"> <u>• This drug should be injected at least 2 to 3 cm apart from the previous injection site.</u> <u>• If any masses and indurations that formed in the injection site are noted, injection into the affected area should be avoided.</u> <p><u>Injection of this drug into areas where cutaneous amyloidosis or lipodystrophy developed may impede the absorption of this drug and result in poor glycemic control. If poor glycemic control is recognized, the injection site should be examined for mass or induration and appropriate measures should be taken such as</u></p>

Pharmaceuticals and Medical Devices Agency

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

	<p><u>changing the injection site as well as dose adjustment. Cases of hypoglycemia have been reported that occurred after the injection site was changed, and insulin preparation was injected into an unaffected area in doses excessively increased in association with the poor glycemic control.</u></p> <p><u>Incorrect doses of insulin may be injected by confusing the number of units of insulin per milliliter of liquid (insulin units) with the volume of the liquid (mL). Syringes dedicated to the insulin vials that are calibrated in insulin units or other measurement units should be used to formulate or administer an injection liquid.</u></p>
--	--

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

Pharmaceuticals and Medical Devices Agency

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