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Revision of Precautions

Insulin human (genetical recombination) (cartridge preparations, prefilled preparations)
Insulin aspart (genetical recombination) (cartridge preparations, prefilled preparations)
Insulin glargine (genetical recombination) (cartridge preparations, prefilled preparations)
Insulin glargine (genetical recombination) [insulin glargine biosimilar 1]
Insulin glargine (genetical recombination) [insulin glargine biosimilar 2]
Insulin glulisine (genetical recombination) (cartridge preparations, prefilled preparations)
Insulin degludec (genetical recombination)
Insulin degludec (genetical recombination)/insulin aspart (genetical recombination)
Insulin detemir (genetical recombination)

May 19, 2020

Therapeutic category

Hormones-miscellaneous

Pharmaceuticals and Medical Devices Agency

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Non-proprietary name

Insulin human (genetical recombination), insulin aspart (genetical recombination), insulin glargine (genetical recombination) [insulin glargine biosimilar 1], insulin glargine (genetical recombination) [insulin glargine biosimilar 2], insulin glulisine (genetical recombination), insulin degludec (genetical recombination), insulin degludec (genetical recombination)/insulin aspart (genetical recombination), insulin detemir (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

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
Important Precautions (N/A)	Important Precautions <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> <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> <u>Injection of this drug into areas where cutaneous amyloidosis or</u>

	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.

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
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS 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: ・This drug should be injected at least 2 to 3 cm apart from the previous injection site. ・If any masses and indurations that formed in the injection site are noted, injection into the affected area should be avoided. Injection of this drug into areas where cutaneous amyloidosis or

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	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.

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