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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Exenatide

Semaglutide (genetical recombination)

Dulaglutide (genetical recombination)

Lixisenatide

Liraglutide (genetical recombination)

Insulin glargine (genetical recombination)/lixisenatide

Insulin degludec (genetical recombination)/liraglutide (genetical recombination)

February 14, 2023

Pharmaceuticals and Medical Devices Agency

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Therapeutic category

Other hormone preparations (including antihormone preparations)

Antidiabetic agents

Non-proprietary name

Exenatide

Semaglutide (genetical recombination)

Dulaglutide (genetical recombination)

Lixisenatide

Liraglutide (genetical recombination)

Insulin glargine (genetical recombination)/lixisenatide

Insulin degludec (genetical recombination)/liraglutide (genetical recombination)

Safety measure

Precautions should be revised.

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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
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Cholelithiasis, cholecystitis, cholangitis, or cholestatic jaundice may occur. If abdominal symptoms such as abdominal pain are observed, appropriate measures should be taken with consideration given to close examination of the cause by imaging tests, etc., if necessary.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Cholecystitis, cholangitis, cholestatic jaundice</u>

N/A: Not Applicable. No corresponding language is included in the current Precautions.

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