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Revision of Precautions

Dulaglutide (genetical recombination)

May 9, 2019

Therapeutic category

Hormones-miscellaneous

Non-proprietary name

Dulaglutide (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Severe diarrhoea, vomiting:</u> <u>Cases with severe diarrhoea and vomiting have also been reported that subsequently caused dehydration, leading to acute kidney injury.</u>

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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Severe diarrhoea, vomiting</u> <u>Cases with severe diarrhoea and vomiting have also been reported that subsequently caused dehydration, leading to acute kidney injury.</u>

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

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