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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Clopidogrel sulfate
Clopidogrel sulfate/aspirin

January 17, 2023

Therapeutic category

Other agents relating to blood and body fluids

Non-proprietary name

Clopidogrel sulfate

Clopidogrel sulfate/aspirin

Safety measure

Precautions should be revised.

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 Insulin autoimmune syndrome: Severe hypoglycaemia may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures, such as discontinuation of administration, should be taken.
Other Precautions It has been reported that insulin autoimmune syndrome, which may cause severe hypoglycaemia, occurred during administration of this drug. Among the patients whose HLA allele was analyzed, there were patients with HLA-DR4 (DRB1*0406), which has been reported to have a strong correlation with the occurrence of insulin autoimmune syndrome. In addition, it has been reported that patients with HLA DR4 subtype are more frequent in the Japanese population.	Other Precautions It has been reported that the occurrence of insulin autoimmune syndrome is strongly correlated with HLA-DR4 (DRB1*0406). In addition, it has been reported that patients with HLA DR4 subtype are more frequent in the Japanese population.

[Reference] Uchigata,Y.,et al.:Diabetes 1995;44(10):1227-1232
Uchigata,Y.,et al.:Human Immunol. 2000;61:154-157

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

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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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A) 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Uses It has been reported that insulin autoimmune syndrome, which may cause severe hypoglycaemia, occurred during administration of this drug. Among the patients whose HLA allele was analyzed, there were patients with HLA-DR4 (DRB1*0406), which has been reported to have a strong correlation with the occurrence of insulin autoimmune syndrome. In addition, it has been reported that patients with HLA DR4 subtype are more frequent in the Japanese population.	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Insulin autoimmune syndrome Severe hypoglycaemia may occur. 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Uses It has been reported that the occurrence of insulin autoimmune syndrome is strongly correlated with HLA-DR4 (DRB1*0406). In addition, it has been reported that patients with HLA DR4 subtype are more frequent in the Japanese population.

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