Published by Ministry of Health, Labour and Welfare

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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 Clopidogrel sulfate

June 1, 2020

Therapeutic category

Blood and body fluid agents-miscellaneous

Non-proprietary name

Clopidogrel sulfate

Safety measure Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Current			Revision		
Contraindications			Contraindications		
Patients receiving selexipag			(deleted)		
Drug Interactions Contraindications for Co-administration			Drug Interactions (deleted)		
Signs symptoms and			(deleted)		
<u>Drugs</u>	treatment	Mechanism/risk factors			
Selexipag	The blood concentration of the active metabolite of selexipag may increase.	Metabolism of the active metabolite of selexipag is considered to be suppressed due to the inhibition of CYP2C8.			
Precautions for Co-administration			Precautions for Co-administration		
(N/A)			Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
			<u>Selexipag</u>	There are reports that the <u>C_{max} and AUC of the active</u> metabolite of selexipag (MRE-269) increased. A dose reduction in selexipag should be considered if co- administered with this drug.	The blood concentration of selexipag is considered to increase due to the inhibition of CYP2C8 by the glucuronic acid conjugate of this drug.

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.

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

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Revision Current 2. CONTRAINDICATIONS 2. CONTRAINDICATIONS Patients receiving selexipag (deleted) **10. INTERACTIONS 10. INTERACTIONS** 10.1 Contraindications for Co-administration (deleted) Signs, symptoms, and Mechanism/risk factors Drugs treatment Selexipag The blood concentration Metabolism of the active of the active metabolite metabolite of selexipad of selexipag is considered to be may suppressed due to the increase. inhibition of CYP2C8 by this drug. 10.2Precautions for Co-administration 10.2 Precautions for Co-administration Signs, symptoms, (N/A) Mechanism/risk factors Drugs and treatment blood concentration of Selexipag There are reports The that the C_{max} and selexipag is considered to increase AUC of the active due to the CYP2C8 inhibiting effects by the glucuronic acid metabolite of selexipag (MREconjugate of this drug. 269) increased. A dose reduction in selexipag should be considered if co-administered with this drug.

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

Revised language is underlined.

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

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