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Pharmaceuticals and Medical Devices Agency

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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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.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>
Contraindications
Patients receiving selexipag

Drug Interactions
Contraindications for Co-administration
<table>
<tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr>
<tr><td>Selexipag</td><td>The blood concentration of the active metabolite of selexipag may increase.</td><td>Metabolism of the active metabolite of selexipag is considered to be suppressed due to the inhibition of CYP2C8.</td></tr>
</table>
Precautions for Co-administration
(N/A)
</td><td>
Contraindications
(deleted)

Drug Interactions
(deleted)

Precautions for Co-administration
<table>
<tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr>
<tr><td>Selexipag</td><td>There are reports that the C_{max} and AUC of the active metabolite of selexipag (MRE-269) increased. A dose reduction in selexipag should be considered if co-administered with this drug.</td><td>The blood concentration of selexipag is considered to increase due to the inhibition of CYP2C8 by the glucuronic acid conjugate of this drug.</td></tr>
</table>
</td></tr>
</table>

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

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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.

<table>
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Patients receiving selexipag

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