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Translated by  
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*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

## Andexanet alfa (genetical recombination)

March 28, 2024

### **Therapeutic category**

Other agents relating to blood and body fluids

### **Non-proprietary name**

Andexanet alfa (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, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision						
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Heparin resistance may be observed. When this drug is administered at the time of surgery/procedure where anticoagulation with heparin is necessary, the necessity of administration of this drug should be carefully determined. The cases in which this drug was used in the perioperative setting and heparin resistance was observed have been reported in both Japan and overseas. Among them, cases have been reported in which the anticoagulant effect of heparin could not be sufficiently obtained, and the extra-corporeal circuit was obstructed by thrombus, resulting in serious outcomes.</u></p> <p>10. INTERACTIONS</p> <p><u>10.2 Precautions for Co-administration</u></p> <table border="1" data-bbox="1146 1023 1995 1313"> <thead> <tr> <th data-bbox="1146 1023 1435 1090">Drugs</th> <th data-bbox="1438 1023 1722 1090">Signs, symptoms, and treatment</th> <th data-bbox="1724 1023 1995 1090">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1146 1091 1435 1313"> <u>Unfractionated heparin</u>  <u>Heparin sodium</u>  <u>Heparin calcium</u>  <u>Low-molecular-weight heparin</u>  <u>Enoxaparin</u> </td> <td data-bbox="1438 1091 1722 1313"> <u>The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.</u> </td> <td data-bbox="1724 1091 1995 1313"> <u>In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the</u> </td> </tr> </tbody> </table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Unfractionated heparin</u> <u>Heparin sodium</u> <u>Heparin calcium</u> <u>Low-molecular-weight heparin</u> <u>Enoxaparin</u>	<u>The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.</u>	<u>In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the</u>
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<p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p><u>This drug may inhibit the anticoagulant effect of heparin. Cases have been reported overseas in which heparin resistance was observed during the surgery due to preoperative administration of this drug.</u></p>	<table border="1" data-bbox="1146 153 1995 284"> <tr> <td data-bbox="1146 153 1435 284"> <u>sodium</u>  <u>Dalteparin sodium</u>  <u>Parnaparin</u>  <u>sodium</u> </td> <td data-bbox="1440 153 1722 284"></td> <td data-bbox="1727 153 1995 284"> <u>anticoagulant effect</u>  <u>of heparin.</u> </td> </tr> </table> <p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>(deleted)</p>	<u>sodium</u> <u>Dalteparin sodium</u> <u>Parnaparin</u> <u>sodium</u>		<u>anticoagulant effect</u> <u>of heparin.</u>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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