

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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)

November 26, 2025

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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Revised language is underlined.

Current			Revision		
<p>8. IMPORTANT PRECAUTIONS</p> <p>After hemostasis is achieved, to reduce the risk of thromboembolism, patients' conditions should be carefully monitored and resumption of anticoagulant therapy should be considered as soon as medically appropriate after the benefit of resuming anticoagulant therapy and the risk of recurrence of haemorrhage are evaluated.</p>			<p>8. IMPORTANT PRECAUTIONS</p> <p>After hemostasis is achieved, to reduce the risk of thromboembolism, patients' conditions should be carefully monitored and resumption of anticoagulant therapy should be considered as soon as medically appropriate after the benefit of resuming anticoagulant therapy and the risk of recurrence of haemorrhage are evaluated. <u>A normal degree of anticoagulation from direct factor Xa inhibitors or low-molecular weight heparin can be expected after 4 hours following the end of administration of this drug based on the simulation results.</u></p>		
<p>10. INTERACTIONS</p> <p>10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)</p>			<p>10. INTERACTIONS</p> <p>10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)</p>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Unfractionated heparin Heparin sodium Heparin calcium Low-molecular weight heparin Enoxaparin sodium	The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.	In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the anticoagulant effect of heparin.	Unfractionated heparin Heparin sodium Heparin calcium	The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.	In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the anticoagulant effect of heparin. <u>The effects of andexanet alfa on the</u>

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Dalteparin sodium Parnaparin sodium					<u>pharmacological action of unfractionated heparin (anticoagulant activity) have not been studied in healthy volunteers or bleeding patients.</u>
			Low-molecular weight heparin Enoxaparin sodium Dalteparin sodium Parnaparin sodium	The anticoagulant effect of heparin may be attenuated, and heparin resistance may be observed.	In vitro data suggests that this drug acts on heparin-antithrombin III complex, and attenuates the anticoagulant effect of heparin. <u>Based on the simulation results, the anticoagulant activity of low-molecular weight heparin is estimated to be affected up to 4 hours following the end of administration of this drug.</u>