独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Andexanet alfa (genetical recombination)

November 26, 2025

Non-proprietary name

Andexanet alfa (genetical recombination)

Brand name (marketing authorization holder)

Ondexxya for Intravenous Injection 200 mg
(AstraZeneca K.K.)

Japanese market launch

May 2022

Indications

The reversal of the anticoagulant effect of a direct-acting factor Xa inhibitor (apixaban, rivaroxaban, or edoxaban tosilate hydrate) in patients experiencing life-threatening or uncontrolled bleeding

Summary of revisions

1. A description to the effect that 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 should be added to the 8. IMPORTANT PRECAUTIONS section.
2. A description to the effect that 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 based on the simulation results should be added to the 10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) section in 10. INTERACTIONS section. Also, a description to the effect

that the effects of andexanet alfa on the pharmacological action of unfractionated heparin (anticoagulant activity) have not been studied should be added.

Investigation results and background of the revision

The results of simulation using the pharmacokinetics / pharmacodynamics models submitted by the marketing authorization holder were evaluated. As a result of consultation with expert advisors, there was no particular problem with the models and simulation results, and provision of information based on the simulation results was judged to be clinically useful. Therefore, MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).