Revision of PRECAUTIONS

Amivantamab (genetical recombination)
Amivantamab (genetical recombination)/vorhyaluronidase alfa (genetical recombination)
Lazertinib mesilate hydrate
Apixaban

March 6, 2026

Therapeutic category

a. b. c. Other antitumor agents

d. Anticoagulants

Non-proprietary name

a. Amivantamab (genetical recombination)

b. Amivantamab (genetical recombination)/vorhyaluronidase alfa (genetical recombination)

c. Lazertinib mesilate hydrate

d. Apixaban

Safety measure

PRECAUTIONS should be revised.

Amivantamab (genetical recombination) Revised language is underlined.

Current	Revision
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with lazertinib, administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with lazertinib, administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment. Pay attention to the risk of bleeding by referring to the electronic package insert of apixaban. Since apixaban cannot be administered in patients with renal failure (creatinine clearance (CLcr) < 15 mL/min), treatment options other than the concomitant use of amivantamab (genetical recombination) and lazertinib should be considered.
9. PRECAUTIONS CONCERNING PERSONS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment <*EGFR* mutation-positive unresectable advanced or recurrent non-small cell lung cancer> Patients with renal failure (CLcr < 15 mL/min) Since apixaban cannot be administered, the concomitant use with lazertinib should be avoided, and other treatment options should be considered.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

Amivantamab (genetical recombination)/vorhyaluronidase alfa (genetical recombination) Revised language is underlined.

Current	Revision
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with lazertinib, administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with lazertinib, administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment. Pay attention to the risk of bleeding by referring to the electronic package insert of apixaban. Since apixaban cannot be administered in patients with renal failure (creatinine clearance (CLcr) < 15 mL/min), treatment options other than the concomitant use of amivantamab (genetical recombination) and lazertinib should be considered.
9. PRECAUTIONS CONCERNING PERSONS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment <*EGFR* mutation-positive unresectable advanced or recurrent non-small cell lung cancer> Patients with renal failure (CLcr < 15 mL/min) Since apixaban cannot be administered, the concomitant use with lazertinib should be avoided, and other treatment options should be considered.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

Lazertinib mesilate hydrate

Revised language is underlined.

Current	Revision
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with amivantamab (genetical recombination), administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION When administering this drug in combination with amivantamab (genetical recombination), administer oral apixaban 2.5 mg twice daily to prevent venous thromboembolism for the first 4 months of treatment. <u>Pay attention to the risk of bleeding by referring to the electronic package insert of apixaban. Since apixaban cannot be administered in patients with renal failure (creatinine clearance (CLcr) < 15 mL/min), treatment options other than the concomitant use of amivantamab (genetical recombination) and lazertinib should be considered.</u>
9. PRECAUTIONS CONCERNING PERSONS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS <u>9.2 Patients with Renal Impairment</u> <u>Patients with renal failure (CLcr < 15 mL/min)</u> <u>Since apixaban cannot be administered, other treatment options should be considered.</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

Apixaban

Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) <Prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation> Patients with Renal Failure (creatinine clearance (CLcr) < 15 mL/min)	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) <Prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation, prevention of venous thromboembolism associated with the concomitant use of amivantamab (genetical recombination) and lazertinib> Patients with Renal Failure (creatinine clearance (CLcr) < 15 mL/min)
9. PRECAUTIONS CONCERNING PERSONS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment <Prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation> Patients with renal failure (CLcr < 15 mL/min) Do not administer this drug. No clinical study to assess the efficacy or safety in patients with renal failure (CLcr < 15 mL/min) has been conducted. Patients with renal disorder (CLcr 15-50 mL/min) The risk of bleeding may increase.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment <Prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation, prevention of venous thromboembolism associated with the concomitant use of amivantamab (genetical recombination) and lazertinib> Patients with renal failure (CLcr < 15 mL/min) Do not administer this drug. No clinical study to assess the efficacy or safety in patients with renal failure (CLcr < 15 mL/min) has been conducted. Patients with renal disorder (CLcr 15-50 mL/min) The risk of bleeding may increase.