RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) for subcutaneous use: Dosing and administration

RYBREVANT FASPRO™ indications and recommended dosing schedule

RYBREVANT FASPRO™ is indicated in adults with locally advanced or metastatic NSCLC with *EGFR*:

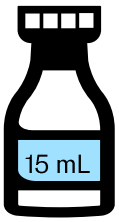
Exon 19 deletions *or* Exon 21 L858R substitution mutations		**Exon 20 insertion mutations**	
1L RYBREVANT FASPRO™ + LAZCLUZE®*	2L RYBREVANT FASPRO™ + carboplatin and pemetrexed	1L RYBREVANT FASPRO™ + carboplatin and pemetrexed	2L RYBREVANT FASPRO™ single agent
Q2W/Q4W	Q3W	Q3W	Q2W/Q4W

*LAZCLUZE® is administered orally daily

RYBREVANT FASPRO™ is supplied at a concentration of 160 mg amivantamab and 2,000 units hyaluronidase per mL in single-dose vials as follows:

10 mL vial
(1,600 mg amivantamab + 20,000 units hyaluronidase)

14 mL vial
(2,240 mg amivantamab + 28,000 units hyaluronidase)



15 mL vial
(2,400 mg amivantamab + 30,000 units hyaluronidase)

22 mL vial
(3,520 mg amivantamab + 44,000 units hyaluronidase)

RYBREVANT FASPRO™ total dose	**Total dose volume**	**Vial sizes needed***
1,600 mg amivantamab and 20,000 units hyaluronidase	10 mL	1x 10 mL
2,240 mg amivantamab and 28,000 units hyaluronidase	14 mL	1x 14 mL
2,400 mg amivantamab and 30,000 units hyaluronidase	15 mL	1x 15 mL
3,360 mg amivantamab and 42,000 units hyaluronidase	21 mL†	1x 22 mL‡
3,520 mg amivantamab and 44,000 units hyaluronidase	22 mL†	1x 22 mL
4,640 mg amivantamab and 58,000 units hyaluronidase	29 mL†	1x 14 mL + 1x 15 mL

*The vial sizes recommended in this infographic optimize use with approved dosing regimens (see page 2) and do not account for dose modifications with RYBREVANT FASPRO™. If different vial sizes are used; discard unused portion. †Divide the dose volume approximately equally into two syringes (each syringe should not exceed 15 mL). ‡Discard unused portion.

Vials: Store RYBREVANT FASPRO™ vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake. **Prepared syringe(s):** If immediate administration is not possible, store the prepared syringes of RYBREVANT FASPRO™ refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours followed by at room temperature of 15°C to 30°C (59°F to 86°F) for up to 24 hours. Discard the prepared syringe(s) if stored for more than 24 hours refrigerated or more than 24 hours at room temperature. If stored in the refrigerator, allow the solution to come to room temperature before administration.

1L, first line; **2L**, second line; **C**, Celsius; **EGFR**, epidermal growth factor receptor; **F**, Fahrenheit; **kg**, kilogram; **mg**, milligram; **mL**, milliliter; **NSCLC**, non-small cell lung cancer; **Q2W**, every 2 weeks; **Q3W**, every 3 weeks; **Q4W**, every 4 weeks.

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RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) for subcutaneous use: Dosing and administration*

Recommended dosage of RYBREVANT FASPRO™ in combination with LAZCLUZE® or as a single agent (every 2- or every 4-week dosing)

Patients currently receiving intravenous RYBREVANT® or subcutaneous RYBREVANT FASPRO™ at an every 2-week dosing regimen may switch to RYBREVANT FASPRO™ at an every 4-week dosing regimen at their next scheduled dose on or after Week 5

Body weight at baseline†
< 80kg

Weekly (total of 4 doses)
Injection on Day 1

RYBREVANT FASPRO™ (mg)

1600	1600	1600	1600

1600 mg:
10 mL required
● 1x10 mL vial

Every 2 weeks
starting at Week 5 onwards until disease progression or unacceptable toxicity

1600	No Dose	1600	No Dose	1600	No Dose	1600	No Dose	1600

Every 4 weeks
starting at Week 5 onwards until disease progression or unacceptable toxicity

3520	No Dose	No Dose	No Dose	3520	No Dose	No Dose	No Dose	3520

3520 mg:
22 mL required, **divided between 2 syringes‡**
● 1x22 mL vial

Body weight at baseline†
≥ 80kg

Weekly (total of 4 doses)
Injection on Day 1

RYBREVANT FASPRO™ (mg)

2240	2240	2240	2240

2240 mg:
14 mL required
● 1x14 mL vial

Every 2 weeks
starting at Week 5 onwards until disease progression or unacceptable toxicity

2240	No Dose	2240	No Dose	2240	No Dose	2240	No Dose	2240

Every 4 weeks
starting at Week 5 onwards until disease progression or unacceptable toxicity

4640	No Dose	No Dose	No Dose	4640	No Dose	No Dose	No Dose	4640

4640 mg:
29 mL required, **divided between 2 syringes‡**
● 1x15 mL + ● 1x14 mL vials

Recommended dosage of RYBREVANT FASPRO™ in combination with carboplatin and pemetrexed (every 3-week dosing)

Patients currently receiving intravenous RYBREVANT® at an every 3-week dosing regimen may switch to subcutaneous RYBREVANT FASPRO™ at an every 3-week dosing regimen at their next scheduled dose on or after Week 4

Body weight at baseline†

First dose at Week 1 Day 1 | Weekly (Weeks 2-3) Injection on Day 1 | **Every 3 weeks** starting at Week 4 onwards until disease progression or unacceptable toxicity

< 80kg

1600	2400	2400	2400	No Dose	No Dose	2400	No Dose	No Dose	2400	No Dose	No Dose	2400

1600 mg:
10 mL required
● 1x10 mL vial

2400 mg:
15 mL required
● 1x15 mL vial

≥ 80kg

2240	3360	3360	3360	No Dose	No Dose	3360	No Dose	No Dose	3360	No Dose	No Dose	3360

2240 mg:
14 mL required
● 1x14 mL vial

3360 mg:
21 mL required, **divided between 2 syringes.‡**
● 1x22 mL vial. Discard unused portion.

kg, kilogram; **mg**, milligram; **mL**, milliliter. *The vial sizes recommended in this infographic optimize use with approved dosing regimens and do not account for dose modifications with RYBREVANT FASPRO™. If different vial sizes are used, discard unused portion. †Dose adjustments not required for subsequent body weight changes. ‡Each syringe should not exceed 15 mL.

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RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) for subcutaneous use: Recommended premedications and prophylactic and concomitant medications

Recommended premedications

Prior to the initial injection of RYBREVANT FASPRO™ (Week 1 Day 1), administer premedications as described below to reduce the risk of administration-related reactions.

- **Glucocorticoid** administration is **required** at the initial dose at **Week 1 Day 1 only**, and upon **re-initiation** after prolonged dose interruptions, **then as necessary** for subsequent injections.
- Administer both **antihistamine and antipyretic prior to all** RYBREVANT FASPRO™ doses.

Medication	Dose	Dosing window prior to RYBREVANT FASPRO™ administration
Antihistamine*	Diphenhydramine (25 mg to 50 mg) or equivalent	Oral: 30-60 mins prior; IV: 15-30 mins prior
Antipyretic*	Acetaminophen (650 mg to 1,000 mg) or equivalent	Oral: 30-60 mins prior; IV: 15-30 mins prior
Glucocorticoid†	Dexamethasone (20 mg) or equivalent	Oral: ≥60 mins prior; IV: 45-60 mins prior
Glucocorticoid‡	Dexamethasone (10 mg) or equivalent	Oral: 60-90mins prior; IV: 45-60 mins prior

*Required at all doses. †Required at initial dose (Week 1, Day 1) or at the next subsequent dose in the event of an administration-related reaction. ‡Optional for subsequent doses.

Prophylactic and concomitant medications to reduce the risk of dermatologic adverse reactions

	Weeks 1-12	Weeks 13-52	Remainder of treatment	2 months post treatment
Oral antibiotic (doxycycline/minocycline, 100 mg orally twice daily)	■			
Antibiotic lotion to the scalp (clindamycin 1% topical once daily)		■		
Non-comedogenic skin moisturizer (ceramide-based or other formulations that provide long-lasting skin hydration and exclude drying agents) on the face and whole body (except scalp)	■	■	■	
Wash hands and feet with 4% chlorhexidine solution once daily	■	■	■	
Limit sun exposure. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen to reduce the risk of dermatologic adverse reactions	■	■	■	■

RYBREVANT FASPRO™ in combination with LAZCLUZE®: Concomitant medications to reduce the risk of venous thromboembolic (VTE) events

When initiating treatment with RYBREVANT FASPRO™ in combination with LAZCLUZE®, **administer anticoagulant prophylaxis** to prevent VTE events for the **first four months of treatment.**

If there are no signs or symptoms of VTE during the first four months of treatment, consider discontinuation of anticoagulant prophylaxis at the discretion of the healthcare provider.

Refer to the LAZCLUZE® prescribing information for information about concomitant medications.

IV, intravenous; **UVA**, ultraviolet A; **UVB**, ultraviolet B; **VTE**, venous thromboembolism

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Safety Information Summary

CONTRAINDICATIONS

RYBREVANT FASPRO™ is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Administration-Related Reactions with RYBREVANT FASPRO™

RYBREVANT FASPRO™ can cause hypersensitivity and administration-related reactions (ARR); signs and symptoms of ARR include dyspnea, flushing, fever, chills, chest discomfort, hypotension, and vomiting. The median time to ARR onset is approximately 2 hours.

Infusion-Related Reactions with RYBREVANT®

RYBREVANT® can cause infusion-related reactions (IRR) including anaphylaxis; signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting. The median time to IRR onset is approximately 1 hour.

Interstitial Lung Disease/Pneumonitis

RYBREVANT FASPRO™ and RYBREVANT® can cause severe and fatal interstitial lung disease (ILD)/pneumonitis.

Venous Thromboembolic (VTE) Events with Concomitant Use with LAZCLUZE®

RYBREVANT FASPRO™ and RYBREVANT® in combination with LAZCLUZE® can cause serious and fatal venous thromboembolic (VTE) events, including deep vein thrombosis and pulmonary embolism. Without prophylactic anticoagulation, the majority of these events occurred during the first four months of treatment.

Dermatologic Adverse Reactions

RYBREVANT FASPRO™ and RYBREVANT® can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus and dry skin.

Ocular Toxicity

RYBREVANT FASPRO™ and RYBREVANT® can cause ocular toxicity including keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus and uveitis.

Embryo-Fetal Toxicity

Based on animal models, RYBREVANT FASPRO™, RYBREVANT® and LAZCLUZE® can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating RYBREVANT FASPRO™ and RYBREVANT®. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT FASPRO™ or RYBREVANT®, and for 3 weeks after the last dose of LAZCLUZE®.

ADVERSE REACTIONS

RYBREVANT FASPRO™ with LAZCLUZE®

In PALOMA-3 (n=206), the most common adverse reactions (≥20%) were rash (80%), nail toxicity (58%), musculoskeletal pain (50%), fatigue (37%), stomatitis (36%), edema (34%), nausea (30%), diarrhea (22%), vomiting (22%), constipation (22%), decreased appetite (22%), and headache (21%).

RYBREVANT® with LAZCLUZE®

In MARIPOSA (n=421), the most common adverse reactions (ARs) (≥20%) were rash (86%), nail toxicity (71%), infusion-related reactions (IRRs) (RYBREVANT®) (63%), musculoskeletal pain (47%), stomatitis (43%), edema (43%), VTE (36%), paresthesia (35%), fatigue (32%), diarrhea (31%), constipation (29%), COVID-19 (26%), hemorrhage (25%), dry skin (25%), decreased appetite (24%), pruritus (24%), and nausea (21%).

RYBREVANT® with Carboplatin and Pemetrexed

In MARIPOSA-2 (n=130), the most common ARs (≥20%) were rash (72%), IRRs (59%), fatigue (51%), nail toxicity (45%), nausea (45%), constipation (39%), edema (36%), stomatitis (35%), decreased appetite (31%), musculoskeletal pain (30%), vomiting (25%), and COVID-19 (21%).

In PAPILLON (n=151), the most common ARs (≥20%) were rash (90%), nail toxicity (62%), stomatitis (43%), IRRs (42%), fatigue (42%), edema (40%), constipation (40%), decreased appetite (36%), nausea (36%), COVID-19 (24%), diarrhea (21%), and vomiting (21%).

RYBREVANT® as a Single Agent

In CHRYSALIS (n=129), the most common ARs (≥20%) were rash (84%), IRR (64%), paronychia (50%), musculoskeletal pain (47%), dyspnea (37%), nausea (36%), fatigue (33%), edema (27%), stomatitis (26%), cough (25%), constipation (23%), and vomiting (22%).

LAZCLUZE® DRUG INTERACTIONS

Avoid concomitant use of LAZCLUZE® with strong and moderate CYP3A4 inducers. Consider an alternate concomitant medication with no potential to induce CYP3A4.

Monitor for adverse reactions associated with a CYP3A4 or BCRP substrate where minimal concentration changes may lead to serious adverse reactions, as recommended in the approved product labeling for the CYP3A4 or BCRP substrate.

Please see full Prescribing Information for RYBREVANT FASPRO™, RYBREVANT®, and LAZCLUZE®.

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