# Subcutaneous Amivantamab and Hyaluronidase-lpuj in HNSCC: Dosing and Administration

## SC Amivantamab Indication in HNSCC[1]

RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) is indicated as a single agent for the treatment of adult patients with recurrent or metastatic HNSCC whose disease has progressed on or after platinum-based chemotherapy and an anti-PD-(L)1 antibody.
**Limitations of use:** RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) is not indicated as a treatment for patients with OPSCC that is HPV-associated (i.e, by p16 IHC).

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

## SC Amivantamab Dosing as a Single Agent in HNSCC: Until Disease Progression or Unacceptable Toxicity[1]

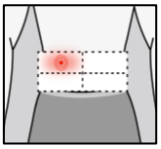
SC amivantamab is supplied at 160 mg/mL amivantamab and 2,000 units/mL hyaluronidase in single-dose vials of 10 mL, 14 mL, 15 mL, and 22 mL

| | SC amivantamab Q3W[a] | | | SC amivantamab Q4W[a] | | |
|---|---|---|---|---|---|---|
| <80 kg | Week 1 Day 1 | 1600 mg | 10 mL required | Weeks 1–4 | 1600 mg | 10 mL required |
| | Weeks 2–3, then Q3W from Week 4 | 2400 mg | 15 mL required | Weeks 5+ | 3520 mg | 22 mL[b] required |
| ≥80 kg | Week 1 Day 1 | 2240 mg | 14 mL required | Weeks 1–4 | 2240 mg | 14 mL required |
| | Weeks 2–3, then Q3W from Week 4 | 3360 mg | 21 mL[b,c] required | Weeks 5+ | 4640 mg | 29 mL[b,d] required |
| | Weekly from Weeks 1 to 3 (injection on Day 1) and **Q3W starting at Week 4 onward** | | | Weekly from Weeks 1 to 4 (injection on Day 1) and **Q4W starting at Week 5 onward** | | |

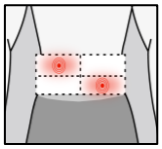
*See the Prescribing Information for recommended premedications and prophylactic and concomitant medications.*

## SC Amivantamab Important Administration Information[1]

- Administer premedications before each SC amivantamab dose as recommended, to reduce the risk of ARRs *(see Dosage and Administration in the Prescribing Information, Section 2.4)*
- For the first dose, monitor patients for hypersensitivity and ARRs for 2 to 4 hours following the end of the injection



- Administer SC amivantamab in the abdomen over ~5 minutes to minimize injection-site irritation.
- Do not inject into tattoos or scars or areas where the skin is red, bruised, tender, hard, not intact, or within 2 inches (5 cm) around the periumbilical area.
- Rotate injection sites at the next scheduled dose.



- If the total dose requires multiple injections of SC amivantamab, administer consecutively in separate abdominal quadrants, approximately 5 minutes per injection; do not exceed 15 mL in each syringe.
- If pain occurs, pause or slow delivery. If pain persists, deliver the remainder at a second site on the opposite side of the abdomen.

## Contraindications[1]

SC amivantamab is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.
Please refer to the Prescribing Information for SC amivantamab for additional safety information.

[a]Dose adjustments are not required for subsequent body weight changes. [b]Divide the dose volume approximately equally into 2 syringes (each ≤15 mL). [c]For 21 mL, the entire 22 mL vial will not be needed. Discard unused portion. [d]For 29 mL, use one 14 mL vial and one 15 mL vial to minimize waste. Discard any unused portion.

ARR, administration-related reaction; HNSCC, head and neck squamous cell carcinoma; HPV, human papillomavirus; IHC, immunohistochemistry; OPSCC, oropharyngeal squamous cell carcinoma; Q3W, every 3 weeks; Q4W, every 4 weeks; SC, subcutaneous.

1. RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) [prescribing information]]. Janssen Biotech, Inc.; 2026.

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Medical Affairs

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# Subcutaneous Amivantamab and Hyaluronidase-lpuj in HNSCC: Dosing and Administration

## Dose Reductions and Dose Modifications for SC Amivantamab in HNSCC[1]

| SC Amivantamab Dose Reductions | | | | | | |
|---|---|---|---|---|---|---|
| **Dose at which AR occurred** | **1600 mg** | **2240 mg** | **2400 mg** | **3360 mg** | **3520 mg** | **4640 mg** |
| 1st dose reduction | 1050 mg | 1600 mg | 1600 mg | 2240 mg | 2400 mg | 3360 mg |
| 2nd dose reduction | 700 mg | 1050 mg | 1050 mg | 1600 mg | 1600 mg | 2240 mg |
| 3rd dose reduction | **Discontinue** | | | | | |

*Dose reductions show amivantamab doses.*

- Refer to the DOSAGE AND ADMINISTRATION, DOSAGE FORMS AND STRENGTHS, CONTRAINDICATIONS (hypersensitivity to hyaluronidase), WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, USE IN SPECIFIC POPULATIONS, and CLINICAL STUDIES sections of the Prescribing Information for SC amivantamab for complete information.[1]
- Click for label-specified guidance on dose modifications and management of adverse reactions with SC amivantamab *(Section 2.8)*[1]

**Click to learn more**
SC Amivantamab Prescribing Information

## SC Amivantamab in HNSCC: Pre-, Prophylactic, and Concomitant Medications[1]

Prior to the initial injection of SC amivantamab, administer premedications as described below:

**Prior to amivantamab**

**ARR prophylactic regimen**

**Antihistamine: diphenhydramine 25 mg to 50 mg[a,b]**
15-30 minutes prior **or** 30-60 minutes prior

**Antipyretic: acetaminophen 650 mg to 1000 mg[a,b]**
15-30 minutes prior **or** 30-60 minutes prior

Administer both antihistamines and antipyretics prior to all SC amivantamab doses

**Glucocorticoid: dexamethasone 20 mg[b,c]**

Glucocorticoid administration is required at the initial dose at Week 1 Day 1 only and upon reinitiation after prolonged dose interruptions, then as necessary for subsequent injections

45-60 minutes prior **or** ≥60 minutes prior

**Glucocorticoid: dexamethasone 10 mg[b,d]**
45-60 minutes prior **or** 60-90 minutes prior

**Begin amivantamab**

**Dermatologic prophylactic regimen**

**Antibiotic prophylaxis**
- **Weeks 1 to 12**: 100 mg doxycycline or minocycline BID
- **Next 9 months**: 1% topical clindamycin lotion on the scalp daily

**Long-acting skin hydration**
- **Week 1+**: Noncomedogenic skin moisturizer[e] on the face and whole body (except scalp)

**Nail-cleaning agent**
- **Week 1+**: Wash hands and feet with 4% chlorhexidine solution once daily

**Limit sun exposure**
- **Week 1 to 2 months post-treatment**: Limit sun exposure during and for 2 months after treatment. Wear protective clothing and use broad-spectrum UVA/UVB sunscreen

AR, adverse reaction; ARR, administration-related reaction; BID, twice daily; IRR, infusion-related reaction; SC, subcutaneous; UV, ultraviolet; VTE, venous thromboembolism.
[a]Required at all doses. [b]Or equivalent. [c]Required at the initial dose (Week 1 Day 1) or at the next subsequent dose in the event of an ARR. [d]Optional for subsequent doses.
[e]Ceramide-based or other formulations that provide long-lasting skin hydration and exclude drying agents.

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