First Infusion Guide

RYBREVANT®
(amivantamab-vmjw)
Injection for IV Use | 350 mg/7 mL (50 mg/mL)

The First Infusion of RYBREVANT®

Know what to expect and ways to manage adult patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations[1]

EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer.

INDICATIONS

RYBREVANT® (amivantamab-vmjw) is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion mutations, as detected by an FDA-approved test.

RYBREVANT® (amivantamab-vmjw) is indicated as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

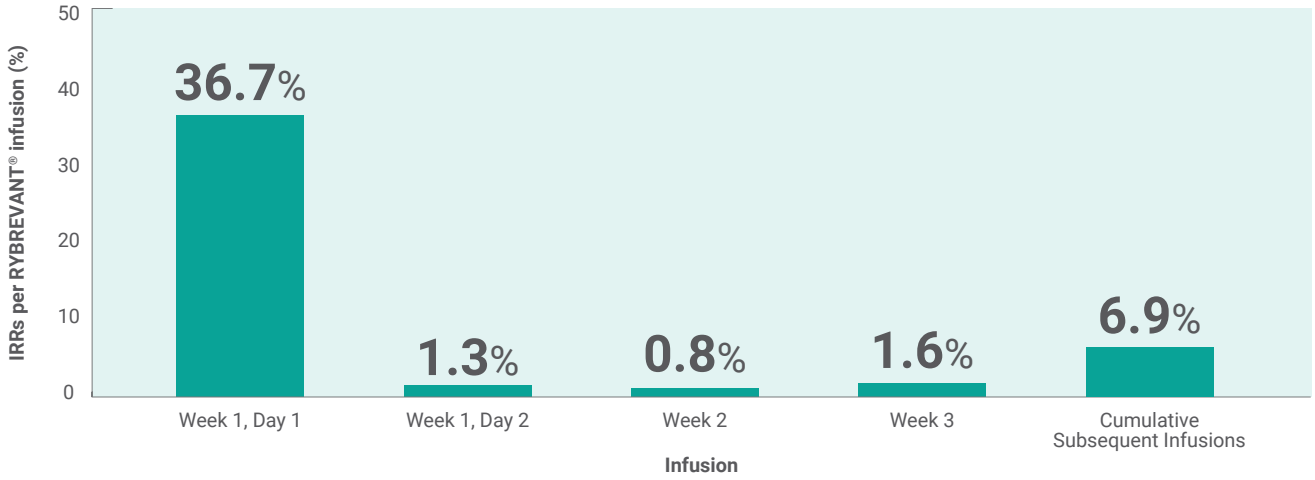
Infusion-Related Reactions

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Knowing what to expect can help you provide necessary supportive care

In the PAPILLON trial, most IRRs occurred during the first infusion (Week 1, Day 1) and rarely during subsequent infusions[2]

- The safety population reflects exposure to RYBREVANT® during the PAPILLON trial (n=151)[2]



- 98.7% of IRRs were Grades 1-2[1,2]
- Median time to onset of first IRR was 0.8 hours (range 0.1-3.6)[2]

Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available[1]

Signs and symptoms of IRRs include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting[1]

- Interrupt infusion if IRR is suspected[1]
- Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity[1]

During treatment with RYBREVANT®, it is important that you and your staff are prepared for any potential IRRs. Remember to advise your patients that RYBREVANT® can cause IRRs, the majority of which may occur with the first infusion, and remind them to alert their healthcare provider immediately of any signs or symptoms of IRRs.[1]

IRR, infusion-related reaction.

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Administer premedications to help reduce the risk of IRRs prior to initial infusion of RYBREVANT® (Week 1, Day 1 and 2)[1]

Medication	Dose	Route of Administration	Dosing Window Prior to RYBREVANT® Administration	Frequency
Antihistamine	Diphenhydramine (25 to 50 mg) or equivalent	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Antipyretic	Acetaminophen (650 to 1,000 mg)	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Glucocorticoid	Dexamethasone (20 mg) or equivalent	Intravenous	45 to 60 minutes	Week 1, Day 1
Glucocorticoid	Dexamethasone (10 mg) or equivalent	Intravenous	45 to 60 minutes	Week 1, Day 2 (optional for subsequent doses)

Glucocorticoid administration required for Week 1, Day 1 and 2 doses only and after re-initiation after prolonged dose interruptions, then as neccessary for subsequent infusions. Administer both antihistamine and antipyretic prior to all infusions.[1]

Administration of RYBREVANT® in combination with carboplatin and pemetrexed (Q3W)

- Administer RYBREVANT® + chemotherapy infusions every 3 weeks intravenously according to the infusion rates
- Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 given the high incidence of infusion-related reactions during initial treatment
- RYBREVANT® may be administered via central line for subsequent weeks
- For the initial infusion, prepare RYBREVANT® as close to administration time as possible to allow for the possibility of extended infusion time in the event of an infusion-related reaction

When administering RYBREVANT® + chemotherapy, infuse pemetrexed first, carboplatin second, and RYBREVANT® last.[1]

For additional dosage and administration guidance for RYBREVANT® (including as a single agent), please see the Prescribing Information.

Q3W, every 3 weeks.

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Dosage modifications & management for ARs

Recommended RYBREVANT® management and dosage modifications for IRRs[1]

Adverse Reaction	Severity	Management & Dose Modifications
Infusion-related reactions (IRRs)	Grades 1-2	• Interrupt RYBREVANT® infusion if IRR is suspected and monitor patient until reaction symptoms resolve • Resume the infusion at 50% of the infusion rate at which the reaction occurred • If there are no additional symptoms after 30 minutes, the infusion rate may be escalated • Include corticosteroid with premedications for subsequent dose
	Grade 3	• Interrupt RYBREVANT® infusion and administer supportive care medications. Continuously monitor patient until reaction symptoms resolve • Resume the infusion at 50% of the infusion rate at which the reaction occurred • If there are no additional symptoms after 30 minutes, the infusion rate may be escalated • Include corticosteroid with premedications for subsequent dose. For recurrent Grade 3, permanently discontinue RYBREVANT®
	Grade 4	• Permanently discontinue RYBREVANT®

AR, adverse reaction.

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Recommended RYBREVANT® management and dosage modifications for other ARs[1]

Adverse Reaction	Severity	Dosage Modifications
Interstitial lung disease (ILD)/ pneumonitis	Any Grade	• Withhold RYBREVANT® if ILD/pneumonitis is suspected • Permanently discontinue RYBREVANT® if ILD/pneumonitis is confirmed
Dermatologic Adverse Reactions (including dermatitis acneiform, pruritus, dry skin)	Grade 1	• Initiate supportive care management • Reassess after 2 weeks
	Grade 2	• Initiate supportive care management • Reassess after 2 weeks; if rash does not improve, consider dose reduction
	Grade 3	• Withhold RYBREVANT® and initiate supportive care management • Upon recovery to ≤Grade 2, resume RYBREVANT® at reduced dose • If no improvement within 2 weeks, permanently discontinue treatment
	Grade 4	• Permanently discontinue RYBREVANT®
	Severe bullous, blistering, or exfoliating skin conditions (including toxic epidermal necrolysis [TEN])	• Permanently discontinue RYBREVANT®
Other Adverse Reactions	Grade 3	• Withhold RYBREVANT® until recovery to ≤Grade 1 or baseline • Resume at the same dose if recovery occurs within 1 week • Resume at reduced dose if recovery occurs after 1 week but within 4 weeks • Permanently discontinue if recovery does not occur within 4 weeks
	Grade 4	• Withhold RYBREVANT® until recovery to ≤Grade 1 or baseline • Resume at reduced dose if recovery occurs within 4 weeks • Permanently discontinue if recovery does not occur within 4 weeks • Permanently discontinue for recurrent Grade 4 reactions

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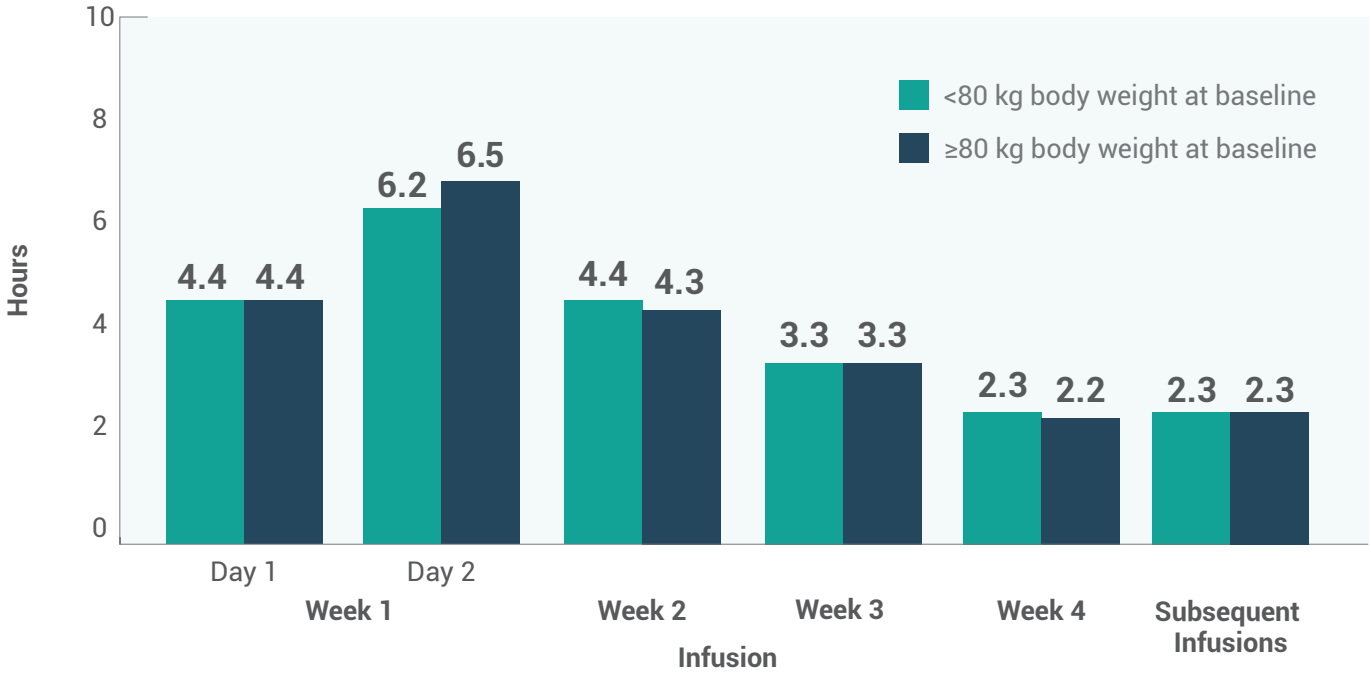
In the PAPILLON trial, infusion times decreased over time with RYBREVANT®[2]

Clinical trial median infusion times by hours*



Total infusion time approximately 4-6 hours for day 1 and 6-8 hours for day 2. Day 2 chair time is longer because of increased dose and decreased infusion rate from Day 1. Subsequent infusion time is approximately 2 hours.[1]

*Data reflect results from 3-week dosing in the PAPILLON study.

Ensure that you and your care team are prepared to manage IRRs and support patients during their first infusion with RYBREVANT®

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RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Premedicate with antihistamines, antipyretics, and glucocorticoids, and infuse RYBREVANT® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2. Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause interstitial lung disease (ILD)/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause rash (including dermatitis acneiform), pruritus, and dry skin.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT® as a single agent.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT®. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen. Alcohol-free emollient cream is recommended for dry skin.

If skin reactions develop, start topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. Withhold, dose reduce, or permanently discontinue RYBREVANT® based on severity.

Ocular Toxicity

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis.

Promptly refer patients presenting with eye symptoms to an ophthalmologist. Withhold, dose reduce, or permanently discontinue RYBREVANT® based on severity.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal models, RYBREVANT® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT®.

Adverse Reactions

RYBREVANT® with Carboplatin and Pemetrexed

The most common adverse reactions (≥20%) were rash, nail toxicity, stomatitis, infusion-related reaction, fatigue, edema, constipation, decreased appetite, nausea, COVID-19, diarrhea, and vomiting. The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased albumin, increased alanine aminotransferase, increased gamma-glutamyl transferase, decreased sodium, decreased potassium, decreased magnesium, and decreases in white blood cells, hemoglobin, neutrophils, platelets, and lymphocytes.

Serious adverse reactions occurred in 37% of patients who received RYBREVANT® in combination with carboplatin and pemetrexed. Serious adverse reactions in ≥2% of patients included rash, pneumonia, ILD, pulmonary embolism, vomiting, and COVID-19. Fatal adverse reactions occurred in 7 patients (4.6%) due to pneumonia, cerebrovascular accident, cardio-respiratory arrest, COVID-19, sepsis, and death not otherwise specified.

RYBREVANT® as a Single Agent

The most common adverse reactions (≥20%) were rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting. The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased glucose, increased alkaline phosphatase, increased gamma-glutamyl transferase, and decreased sodium.

Serious adverse reactions occurred in 30% of patients who received RYBREVANT®. Serious adverse reactions in ≥2% of patients included pulmonary embolism, pneumonitis/ILD, dyspnea, musculoskeletal pain, pneumonia, and muscular weakness. Fatal adverse reactions occurred in 2 patients (1.5%) due to pneumonia and 1 patient (0.8%) due to sudden death.

Please see Sections 5 and 6 in the Prescribing Information for additional information.

Please read full Prescribing Information for RYBREVANT®.

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Reach out to an oncology clinical educator (OCE)

OCEs are oncology nurses employed by Johnson & Johnson to provide product/non-product specific education and informational resources to oncology patient care team members, patient support groups, and advocacy organizations.

Scan or click to learn more and get help from an OCE

Starting and staying on track with a new medication can feel overwhelming for patients. *Janssen Compass*® Care Navigators are here to help by offering free, personalized 1-on-1 support throughout their treatment journey.

Get your patient connected with a Care Navigator

- Call *Janssen Compass*® at **844-628-1234**, Monday through Friday, 8:30 AM-8:30 PM ET
  OR
- Schedule your patient for an introductory call from a Care Navigator here: **JanssenCompass.com/signup**

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References:

1. RYBREVANT® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

2. Data on file. Janssen Biotech, Inc.

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