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

What to Expect With RYBREVANT® Treatment

Know which steps to take if your patients experience dermatologic adverse reactions during treatment

INDICATION

RYBREVANT® (amivantamab-vmjw) is indicated for the 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, whose disease has progressed on or after platinum-based chemotherapy.

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 the confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

RYBREVANT® can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Based on the safety population, IRR occurred in 66% of patients treated with RYBREVANT®. Among patients receiving treatment on Week 1 Day 1, 65% experienced an IRR, while the incidence of IRR was 3.4% with the Day 2 infusion, 0.4% with the Week 2 infusion, and cumulatively 1.1% with subsequent infusions. Of the reported IRRs, 97% were Grade 1-2, 2.2% were Grade 3, and 0.4% were Grade 4. The median time to onset was 1 hour (range 0.1 to 18 hours) after start of infusion. The incidence of infusion modifications due to IRR was 62% and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

Skin rash can be common when being treated with RYBREVANT® (amivantamab-vmjw), but can also be manageable[1]

Knowing what to expect can help you manage these adverse events

In the CHRYSALIS trial, RYBREVANT® was associated with rash (including dermatitis acneiform), pruritus, and dry skin.[1]

- Rash occurred in 74% of patients treated with RYBREVANT®
- Grade 3 rash occurred in 3.3% of patients
- The median time to onset of rash was 14 days (range: 1 to 276 days)
- Rash leading to dose reduction occurred in 5% of patients
- RYBREVANT® was permanently discontinued due to rash in 0.7% of patients
- Toxic epidermal necrolysis (TEN) occurred in one patient (0.3%) treated with RYBREVANT®

The safety population described above reflect exposure to RYBREVANT® as a single agent in the CHRYSALIS study in 302 patients with locally advanced or metastatic NSCLC who received a dose of 1050 mg (for patients <80 kg) or 1400 mg (for patients ≥80 kg) once weekly for 4 weeks, then every 2 weeks thereafter. Among 302 patients who received RYBREVANT®, 36% were exposed for 6 months or longer and 12% were exposed for greater than one year.[1]

NSCLC, non-small cell lung cancer.

WARNINGS AND PRECAUTIONS (CONTINUED)

Infusion-Related Reactions (CONTINUED)

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.

There are ways to proactively manage dermatologic adverse reactions

Advise patients[1]:

- Of the risk of dermatologic adverse reactions
- To limit direct sun exposure
- To use broad-spectrum UVA/UVB sunscreen and wear sun-protective clothing during treatment
- To apply alcohol-free emollient cream to dry skin

You can help manage these adverse reactions. Please see the "Dosage Modifications" table on page 5

Please read Important Safety Information throughout and on pages 6-7.
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If patients being treated with RYBREVANT® (amivantamab-vmjw) experience skin rash, withhold, dose reduce or permanently discontinue RYBREVANT® based on severity[1]

If skin reactions develop[1]:

- 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

If dose reductions for adverse reactions are needed, follow this guide[1]:

Body Weight of Patient at Baseline	Initial Dose	1st Dose Reduction	2nd Dose Reduction	3rd Dose Reduction
Less than 80 kg	1050 mg	700 mg	350 mg	Discontinue RYBREVANT®
Greater than or equal to 80 kg	1400 mg	1050 mg	700 mg	

Inform patients of the risk of dermatologic adverse reactions with RYBREVANT®

WARNINGS AND PRECAUTIONS (CONTINUED)

Interstitial Lung Disease/Pneumonitis

RYBREVANT® can cause interstitial lung disease (ILD)/pneumonitis. Based on the safety population, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT®, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) discontinued RYBREVANT® due to 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.

Recommended RYBREVANT® Dosage Modifications for Dermatologic Adverse Reactions[1]

Dermatologic Adverse Reactions
(including dermatitis acneiform, pruritus, dry skin)

Grade 2	Grade 3	Grade 4	Severe bullous, blistering or exfoliating skin conditions (including toxic epidermal necrolysis (TEN)
• Initiate supportive care management • Reassess after 2 weeks; if rash does not improve, consider dose reduction	• 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	• Permanently discontinue RYBREVANT®	• Permanently discontinue RYBREVANT®

See the full Prescribing Information for RYBREVANT® for more guidance

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

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® can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis. Based on the safety population, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients treated with RYBREVANT®. All events were Grade 1-2. 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 final dose of RYBREVANT®.

Adverse Reactions
The most common adverse reactions (≥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%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased lymphocytes (8%), decreased albumin (8%), decreased phosphate (8%), decreased potassium (6%), increased alkaline phosphatase (4.8%), increased glucose (4%), increased gamma-glutamyl transferase (4%), and decreased sodium (4%).

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Visit RYBREVANTHCP.com to learn more

If you have questions, ask a Janssen Oncology Clinical Educator!

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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

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