

Adverse Reactions Management Guide

The first and only c-Met targeted ADC for adult patients with 2L+ advanced/metastatic NSq NSCLC with high c-Met protein overexpression (3+, $\geq 50\%$)^{1*}

* $\geq 50\%$ of tumor cells with strong (3+) c-Met (MET) staining.

INDICATION

EMRELIS is indicated for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [$\geq 50\%$ of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

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

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Peripheral neuropathy, interstitial lung disease/pneumonitis, ocular surface disorders, infusion-related reactions, and embryo-fetal toxicity.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions ($\geq 20\%$) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

2L=second line; ADC=antibody-drug conjugate; NSCLC=non-small cell lung cancer; NSq=non-squamous.

Please see full Important Safety Information on pages 14-15.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.

Introduction

This guide was developed to help you understand and manage the adverse reactions that may occur in your patients receiving EMRELIS (telisotuzumab vedotin-tllv).

With all treatments, you have an important role in monitoring patients for adverse reactions, managing dose modifications or interruptions when needed, and providing supportive care. Ultimately, your efforts may help your patients stay on treatment with EMRELIS.

MET IHC testing can help identify patients for EMRELIS treatment.¹ Please refer to page 16 for testing labs where the VENTANA MET (SP44) RxDx Assay may be available.

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IHC=immunohistochemistry.

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Warnings and Precautions¹

Peripheral Neuropathy

EMRELIS can cause peripheral neuropathy, including peripheral sensory neuropathy and peripheral motor neuropathy. In the safety population, peripheral neuropathy occurred in 51% of patients treated with EMRELIS, including Grade 3 in 11%. These adverse reactions included peripheral sensory neuropathy in 45% of patients and peripheral motor neuropathy in 9%. The median time to onset of peripheral neuropathy was 105 days (range: 1 to 472 days). Peripheral neuropathy led to permanent discontinuation of EMRELIS in 13% of patients. The median time to onset of peripheral neuropathy leading to treatment discontinuation was 249 days (range: 57 to 519 days). Of the 7 patients with motor neuropathy ongoing as of their last dose of EMRELIS, 6 had persistent Grade 1 or 2 symptoms 30 days after their last dose.

Monitor patients for signs and symptoms of new or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness. Withhold, reduce the dose, or permanently discontinue EMRELIS based on severity.

Interstitial Lung Disease/Pneumonitis

EMRELIS can cause severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis. In the safety population, ILD/pneumonitis occurred in 10% of patients treated with EMRELIS, including Grade 3 in 3% and Grade 4 in 0.6%. There were 3 fatal cases of ILD/pneumonitis in patients who received EMRELIS. The median time to onset of ILD/pneumonitis was 48 days (range: 23 to 85 days). ILD/pneumonitis led to permanent discontinuation of EMRELIS in 7% of patients. The median time to onset of ILD/pneumonitis leading to treatment discontinuation was 46 days (range: 23 to 85 days).

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD/pneumonitis. Withhold or permanently discontinue EMRELIS based on severity.

Ocular Surface Disorders

EMRELIS can cause ocular surface disorders, including blurred vision, visual impairment, keratitis, and dry eye. In the safety population, ocular surface disorders occurred in 25% of patients treated with EMRELIS. The most common ocular surface disorders were blurred vision (15%), keratitis (11%), and dry eye (5%). Grade 3 ocular surface disorders occurred in 1.2% of patients [blurred vision (1.2%), and keratitis (0.6%)]. The median time to onset of ocular surface disorders was 47 days (range: 1 to 319 days).

Ocular Surface Disorders (cont'd)

Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥ 2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Infusion-Related Reactions

EMRELIS can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, chills, nausea, chest discomfort, and hypotension. The median time to onset of IRR was 28 days (range: 1 to 43 days). In the safety population, IRR occurred in 3% of patients treated with EMRELIS, including Grade 3 in 1.2% and Grade 4 in 0.6%. IRR led to permanent discontinuation of EMRELIS in 0.6% of patients.

Monitor patients for signs and symptoms of infusion reactions during EMRELIS infusion. Withhold, reduce the rate of infusion, or permanently discontinue EMRELIS based on severity. For patients who experience IRR, administer premedications prior to subsequent infusions.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, EMRELIS can cause fetal harm when administered to a pregnant woman. The small molecule component of EMRELIS, monomethyl auristatin E (MMAE), administered to rats caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures similar to those occurring clinically at the recommended dose.

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with EMRELIS and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with EMRELIS and for 4 months after the last dose.

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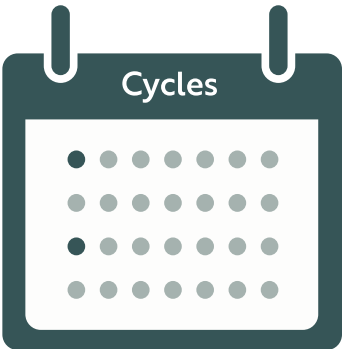
Starting Patients on EMRELIS¹

EMRELIS dosing schedule:

Recommended dosage: 1.9 mg/kg (up to a maximum of 190 mg for patients greater than or equal to 100 kg) administered every 2 weeks until disease progression or unacceptable toxicity

EMRELIS is an IV infusion administered over 30 minutes

-  EMRELIS contains a hazardous component. Follow applicable special handling and disposal procedures in accordance with local requirements
-  Reconstitute and further dilute EMRELIS prior to IV infusion



Please see Section 2.5 Instructions for Preparation and Administration of the Prescribing Information for more detailed instructions on preparation, reconstitution, and administration.

Strong CYP3A Inhibitors:

Concomitant use with strong CYP3A inhibitors may increase unconjugated MMAE AUC which may increase the risk of EMRELIS adverse reactions. Monitor patients for adverse reactions when EMRELIS is given concomitantly with strong CYP3A inhibitors.

No specific dose adjustment required for:



Mild hepatic impairment^{1*}

Avoid use of EMRELIS in patients with moderate or severe hepatic impairment[†]

^{*}Total bilirubin ≤ULN and AST >ULN or total bilirubin >ULN and ≤1.5 x ULN and any AST.
[†]Total bilirubin >1.5 x ULN and any AST.
AST=aspartate aminotransferase; AUC=area under the curve; EGFR=epidermal growth factor receptor; IV=intravenous; MMAE=monomethyl auristatin E; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; ULN=upper limit of normal; wt=wild-type.

Safety and Tolerability Profile¹

LUMINOSITY clinical trial

The safety of EMRELIS was evaluated in the LUMINOSITY study, which included 168 patients with locally advanced or metastatic EGFR wt NSq NSCLC with c-Met protein overexpression who received EMRELIS.

Adverse Reactions (≥10% in LUMINOSITY)	EMRELIS (N=168)	
	All Grades [‡] (%)	Grade 3 or 4 [‡] (%)
Nervous system disorders		
Peripheral neuropathy [§]	51	11
General disorders and administration site conditions		
Fatigue [§]	29	3.6
Peripheral edema [§]	22	1.8
Metabolism and nutrition disorders		
Decreased appetite	22	0.6
Gastrointestinal disorders		
Nausea	15	0
Constipation	14	0.6
Vomiting	10	0.6
Eye disorders		
Blurred vision	15	1.2
Keratitis [¶]	11	0.6
Infections and infestations		
Pneumonia [§]	13	6
Respiratory, thoracic and mediastinal disorders		
ILD/pneumonitis [§]	10	3.6

Serious adverse reactions occurred in 35% of patients. Serious adverse reactions occurring in ≥2% of patients included ILD/pneumonitis (5%), pneumonia (5%), peripheral neuropathy (3.6%), and pleural effusion (2.4%). Fatal adverse reactions occurred in 5% of patients who received EMRELIS, including ILD/pneumonitis (1.8%), pneumonia (1.2%), sudden death (1.2%), noninfectious endocarditis (0.6%) and myocardial infarction (0.6%).

[‡]Events were graded using NCI CTCAE version 4.03.
[§]Grouped term.
^{||}Includes vision blurred, visual acuity reduced, visual impairment.
[¶]Includes corneal cyst, corneal disorder, corneal erosion, corneal edema, corneal opacity, keratitis, keratitis interstitial, punctate keratitis.

Please see full Important Safety Information on pages 14-15.
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Safety and Tolerability Profile (cont'd)¹

Other clinically relevant adverse reactions in <10% of patients who received EMRELIS included arthralgia, dizziness, dry eye, infusion-related reaction, and photophobia.

Select laboratory abnormalities (≥10%) that worsened from baseline in patients on EMRELIS (N=168)

Laboratory abnormality	All Grades (%)	Grade 3 or 4 (%)
Chemistry		
Albumin decreased	61	0.6
Glucose increased	58	4.8
Calcium decreased	47	2.4
Alanine transaminase increased	41	4.8
Gamma glutamyl transferase increased	36	4.3
Aspartate aminotransferase increased	34	0.6
Phosphorus decreased	33	4.2
Sodium decreased	30	3.6
Alkaline phosphatase increased	30	0.6
Creatinine increased	16	1.2
Potassium decreased	14	1.2
Magnesium decreased	14	0.6
Glucose decreased	11	0
Magnesium increased	10	0
Hematology		
Lymphocytes decreased	37	10
Hemoglobin decreased	35	3.6
White blood cells decreased	16	1.2
Platelets decreased	14	0.6
Neutrophils decreased	10	1.2

Percentages were calculated using patients with worsening laboratory values from baseline and the number of patients with both baseline and post-treatment measurements as the denominator.

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Discontinuations, Interruptions, and Dose Reductions¹

Permanent discontinuations of EMRELIS due to adverse reactions occurred in 30% of patients. Adverse reactions which resulted in permanent discontinuation of EMRELIS in ≥2% of patients included peripheral neuropathy, and ILD/pneumonitis



- Peripheral Neuropathy:**
- The median time to onset: 105 days (range: 1-472 days)
 - The median time to onset leading to treatment discontinuation: 249 days (range: 57-519 days)
- ILD/Pneumonitis:**
- The median time to onset: 48 days (range: 23-85 days)
 - The median time to onset leading to treatment discontinuation: 46 days (range: 23-85 days)



Dosage interruptions due to adverse reactions occurred in 44% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included peripheral neuropathy, fatigue, pneumonia, increased ALT, blurred vision, COVID-19, ILD/pneumonitis, and keratitis



Dose reductions due to adverse reactions occurred in 28% of patients. Adverse reactions which required dose reductions in ≥2% of patients included peripheral neuropathy, fatigue, and keratitis

Serious adverse reactions occurred in 35% of patients. Serious adverse reactions occurring in ≥2% of patients included ILD/pneumonitis (5%), pneumonia (5%), peripheral neuropathy (3.6%), and pleural effusion (2.4%). Fatal adverse reactions occurred in 5% of patients who received EMRELIS, including ILD/pneumonitis (1.8%), pneumonia (1.2%), sudden death (1.2%), noninfectious endocarditis (0.6%) and myocardial infarction (0.6%).

ALT=alanine transaminase.

Manage Certain Adverse Reactions With Dose Modifications¹

Recommended dose reductions		
Starting dose	⇒	1.9 mg/kg (up to a maximum of 190 mg for patients ≥100 kg) every 2 weeks until disease progression or unacceptable toxicity
First dose reduction	⇓	1.6 mg/kg every 2 weeks
Second dose reduction	⇓⇓	1.3 mg/kg every 2 weeks
Third dose reduction	⇓⇓⇓	1.0 mg/kg every 2 weeks
Permanently discontinue EMRELIS in patients who are unable to tolerate 1 mg/kg.		

See Section 2.3 of the Prescribing Information and following pages for specific recommended dosage modifications for adverse reactions.

SELECT IMPORTANT SAFETY INFORMATION

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with EMRELIS may increase the area under the curve of MMAE. Monitor for increased risk of adverse reactions to EMRELIS.

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Manage Certain Adverse Reactions With Dose Modifications (cont'd)^{1*}

Adverse reaction	Severity	Dosage modification
Peripheral neuropathy	Grade 2 or 3	- Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
	Grade 4	Permanently discontinue EMRELIS
ILD/Pneumonitis	Grade 1	- Withhold EMRELIS and consider corticosteroids as soon as ILD/pneumonitis is suspected - Resume EMRELIS upon radiographic resolution
	Grade ≥2	Permanently discontinue EMRELIS
Keratitis	Grade 2	- Withhold EMRELIS - Refer patients to an eye care professional for an ophthalmic examination and treatment (e.g., lubricating and/or steroidal eye drops) - Resume EMRELIS at the same dose at the discretion of the healthcare provider
	Grade 3 or 4	- Refer patients to an eye care professional for an ophthalmic examination and treatment (e.g., lubricating and/or steroidal eye drops) - Permanently discontinue EMRELIS
Infusion-related reactions (IRR)	Grade 1-3	- Interrupt EMRELIS infusion and administer supportive treatment - Resume the infusion at a 50% rate reduction. Increase infusion rate as tolerated for subsequent doses - For patients who experience an IRR, administer premedications prior to all future doses (See table on this page)
	Grade 4	- Permanently discontinue EMRELIS - Administer supportive treatment

Adverse reaction	Severity	Dosage modification	
Peripheral edema	Grade ≥2	<u>First occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the same dose level	<u>Subsequent occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
Other adverse reactions	Grade 3	<u>First occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the same dose	<u>Subsequent occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
	Grade 4	Permanently discontinue EMRELIS	

^{*}Events were graded using NCI CTCAE version 4.03.

Adverse reactions

The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased ALT, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

Recommended premedications for patients who experienced infusion-related reactions for subsequent infusions

Medication class	Examples or equivalent	Dose	Route of administration	Dosing window prior to EMRELIS administration
H1 Antihistamine	Diphenhydramine	25 to 50 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
H2 Antihistamine	Famotidine	20 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
Antipyretic	Acetaminophen	650 to 1,000 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
Glucocorticoid	Methylprednisolone	125 mg or equivalent	Intravenously	Administer 30-60 minutes prior to each infusion

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INDICATION

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Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Infusion-Related Reactions

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Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with EMRELIS and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with EMRELIS and for 4 months after the last dose.

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Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with EMRELIS may increase the area under the curve of MMAE. Monitor for increased risk of adverse reactions to EMRELIS.

Use in Specific Populations

Severe or Moderate Hepatic Impairment: Avoid the use of EMRELIS.

Lactation: Advise lactating women not to breastfeed during treatment with EMRELIS and for 1 month after the last dose.

Infertility: Based on findings from animal studies, EMRELIS may impair fertility in females and males.

REFERENCES: 1. EMRELIS [package insert]. North Chicago, IL: AbbVie Inc.; 2025. 2. Roche Diagnostics. VENTANA MET (SP44) Rx Dx Assay Method Sheet. Roche; 2025.

Please see accompanying full **Prescribing Information** or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Support for Your Practice

How to order MET IHC testing



The VENTANA MET (SP44) RxDx Assay is a companion diagnostic to identify NSCLC patients with high c-Met protein overexpression (3+, ≥50%)^{1,2}

Testing may be available at various labs throughout the United States. The following locations offer the VENTANA MET (SP44) RxDx Assay:



Information is intended as educational only for U.S. patients only, is not intended as a complete listing of available testing options and is not regularly updated. While diagnostic testing may assist providers in identifying appropriate treatment for patients, the decision and action should be decided by a provider in consultation with a patient. AbbVie is not affiliated with, and does not endorse, any of the listed laboratories. AbbVie shall have no liability arising from testing at listed laboratories. The information provided here should in no way be considered a guarantee of coverage, reimbursement, availability, or patient assistance. Providers should contact third-party laboratories for information. All trademarks are properties of their respective owners. AbbVie received permission from third-party laboratories for all use of their logos, company names, and associated information.

How to order EMRELIS



EMRELIS can be purchased from the following Specialty Distributors:

How to order EMRELIS		
Distributor name	Telephone number	Website/Email address
Alivia Specialty Pharmacy (for Puerto Rico ONLY)	787-925-1999	farmaciaespecializada@aliviahealth.com aliviasp@aliviahealth.com
Biologics by McKesson	800-850-4306	biologics.mckesson.com
Cardinal Health Specialty Pharmaceutical Distribution	877-453-3972	specialtyonline.cardinalhealth.com
Cencora ASD Healthcare	800-746-6273	www.asdhealthcare.com
Cencora Oncology Supply	800-633-7555	www.oncologysupply.com
McKesson Plasma and Biologics (Hospitals, IDNs, VA)	877-625-2566	MPBOrders@mckesson.com
McKesson Specialty Health (MD Offices)	800-482-6700	mscs.mckesson.com

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