ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

Instructions for General Electronic Health Record (EHR) Systems to Optimize Order Sets With ELAHERE® (mirvetuximab soravtansine-gynx)

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

FDA=US Food and Drug Administration.

Please see Important Safety Information for ELAHERE, including Boxed Warning on pages 3-4, and click to access full Prescribing Information.

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Indication and Important Safety Information

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INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

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- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

WARNINGS and PRECAUTIONS

Ocular Disorders

ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with ELAHERE. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of ELAHERE in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE.

Pneumonitis occurred in 10% of patients treated with ELAHERE, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of ELAHERE in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on page 4, and click to access full Prescribing Information.

Indication and Important Safety Information (cont'd)

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WARNINGS and PRECAUTIONS

Embryo-Fetal Toxicity

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

Hepatic Impairment

Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see full Prescribing Information, including BOXED WARNING

Background and Considerations

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

This document is intended to provide health systems with instructions to update appropriate order sets with ELAHERE in general EHR systems and for no other purpose. The instructions are not fully inclusive of all details of the ELAHERE Prescribing Information, and the clinical data elements are suggestions only. The customer must determine the final elements to include in line with the organization's expectations, goals, and EHR governing principles.

These instructions will not work for other conditions, treatments, or therapeutic areas. This document is not intended to provide any clinical advice or clinical recommendations, which are solely the responsibility of the clinician and health system.

The process outlined below is variable and not all steps will apply to every health system. Any steps or settings below that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Please refer to Clinical Specifications on pages 7-10 for a quick reference guide on the usage of ELAHERE. Please consult the most recent version of the ELAHERE package insert for full medication details. The most recent version of the package insert can be found at **https://www.rxabbvie.com/pdf/elahere_pi.pdf**

Indication

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

Patient Selection

Select patients for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer with ELAHERE based on the presence of FRα tumor expression using an FDA-approved test.

Information on FDA-approved tests for the measurement of FRα tumor expression is available at **http://www.fda.gov/CompanionDiagnostics**

FRα Test

Confirm the FRα test is available in the lab catalog of the health system so it can be ordered. If the FRα test is not available, add the test as a procedure order according to the health system preferences and standard EHR conventions. Consider adding any additional information as desired (LOINC codes and charge/billing information).

FRα Testing

Procedural type	CPT® Code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

The FRα test can be evaluated at these 4 participating lab partners:

- Labcorp
- NeoGenomics
- Caris Life Sciences
- LMC Pathology Services

CPT=Current Procedural Terminology; LOINC=Logical Observation Identifiers Names and Codes.

Background and Considerations (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Recommended Dosing

- Administer ELAHERE as an intravenous infusion only after dilution in 5% Dextrose Injection, USP. ELAHERE is incompatible with normal saline.
- The recommended dose of ELAHERE is 6 mg/kg adjusted ideal body weight administered as an intravenous infusion every 3 weeks until disease progression or unacceptable toxicity.
- Premedicate with a corticosteroid, antihistamine, and antipyretic.
- Premedicate with an antiemetic, ophthalmic topical steroids, and lubricating eye drops.
- See full Prescribing Information for preparation and administration instructions and dose modifications for adverse reactions.

Dosage Form and Strength

Injection: 100 mg/20 mL (5 mg/mL) in a single-dose vial (NDC 72903–853–01).

Helpful Links

- ELAHERE Prescribing Information: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**
- ELAHERE patient information: **www.elahere.com**
- ELAHERE healthcare provider website: **www.elaherehcp.com**

NDC=National Drug Code.

ELAHERE Clinical Specifications Order Set Considerations

The Clinical Specifications Guide provides a high-level overview of treatment considerations and dosing instructions for ELAHERE. For detailed step-by-step instructions, please refer to pages 11-14 on how to optimize order sets for the use of ELAHERE.

Regimen Name (Display Name)

ELAHERE (mirvetuximab soravtansine-gynx) 6 mg/kg AIBW every 3 weeks

ELAHERE Treatment Calendar: 6 mg/kg AIBW

	Cycle (21 days)	**Until disease progression or unacceptable toxicity**
	Day	**1**
Component	**Starting dose**	
ELAHERE	6 mg/kg AIBW	Day 1 only

AIBW Calculation – AdjBW* (also referred to as Adjusted Body Weight. Use the Adjusted Body Weight as an alternative as it may already be available in the EHR):

AIBW using the following formula:

AIBW = Ideal Body Weight (IBW [kg]) + 0.4 × (Actual weight [kg] – IBW)

Female IBW (kg) = 0.9 × height (cm) – 92

*AIBW is equivalent to AdjBW.

Dose Reductions

	ELAHERE Dose Levels
First Dose Reduction	5 mg/kg AIBW once every 3 weeks (21-day cycle)
Second Dose Reduction	4 mg/kg AIBW once every 3 weeks (21-day cycle)†

†Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.

ELAHERE Clinical Specifications Order Set Considerations (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Dose Modifications for Adverse Reactions

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
Keratitis/Keratopathy *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Nonconfluent superficial keratitis	Monitor.
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected visual acuity	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction.
	Corneal ulcer or stromal opacity or best corrected distance visual acuity 20/200 or worse	Withhold until improved or resolved, then reduce by one dose level.
	Corneal perforation	Permanently discontinue.
Uveitis *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Grade 1/Rare cell in anterior chamber	Monitor.
	Grade 2/1–2+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then maintain dose at same dose level.
	Grade 3/3+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then reduce dose by one dose level.
	Grade 4/Hypopyon	Permanently discontinue.
Pneumonitis *[see Warnings and Precautions (5.2) and Adverse Reactions (6.1)]*	Grade 1	Monitor.
	Grade 2	Withhold until Grade 1 or less, then maintain at same dose level or consider dose reduction.
	Grade 3 or 4	Permanently discontinue.
Peripheral Neuropathy *[see Warnings and Precautions (5.3) and Adverse Reactions (6.1)]*	Grade 2	Withhold until Grade 1 or less, then reduce by one dose level.
	Grade 3 or 4	Permanently discontinue.
Infusion-Related Reactions/ Hypersensitivity *[see Adverse Reactions (6.1)]*	Grade 1	Maintain infusion rate.
	Grade 2	• Interrupt infusion and administer supportive treatment. • After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed *[see Dosage and Administration (2.5)]*. • Administer additional premedication for future cycles *[see Dosage and Administration (2.3)]*.
	Grade 3 or 4	• Immediately stop infusion and administer supportive treatment. • Advise patient to seek emergency treatment and immediately notify their healthcare provider if the infusion-related symptoms recur. • Permanently discontinue.
Hematological *[see Adverse Reactions (6.1)]*	Grade 3 or 4	Withhold until Grade 1 or less, then resume at one lower dose level.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	Withhold until Grade 1 or less, then resume at one lower dose level.
	Grade 4	Permanently discontinue.

*Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

ELAHERE Clinical Specifications Order Set Considerations (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Additional Information

Indication/disease	ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.
References	ELAHERE® **Prescribing Information**
Regimen keywords	ELAHERE, mirvetuximab, epithelial ovarian, fallopian tube, or primary peritoneal cancer
Regimen type	Antibody-drug conjugate
Number of cycles	Until disease progression or unacceptable toxicity
Days per cycle	21 days
Maximum duration	Until disease progression or unacceptable toxicity
Safety information/ warnings	Refer to sections 5 and 6 of the **Prescribing Information**
Emetogenic risk	Please refer to your system guidelines when entering this information
Febrile neutropenic risk	Please refer to your system guidelines when entering this information
Premedications	• Corticosteroid, IV, at least 30 minutes prior to ELAHERE • Antihistamine, oral or IV, at least 30 minutes prior to ELAHERE • Antipyretic, oral or IV, at least 30 minutes prior to ELAHERE • Antiemetic, oral or IV, before each dose and thereafter as needed
Required eye care	• *Ophthalmic exam:* Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated. • *Ophthalmic Topical Steroids:* The use of ophthalmic topical steroids is recommended. The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer one drop of ophthalmic topical steroids in each eye 6 times daily starting the day prior to each infusion until day 4; then administer one drop in each eye 4 times daily for days 5–8 of each cycle of ELAHERE *[see Warnings and Precautions (5.1)]*. • *Lubricating Eye Drops:* The use of lubricating eye drops at least four times daily and as needed is recommended during treatment with ELAHERE. Instruct patients to use lubricating eye drops and advise to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops *[see Warnings and Precautions (5.1)]*.
Take home medications	Please refer to your system guidelines when entering this information (see Premedications and Required Eye Care, listed above)
Imaging	Please refer to your system guidelines when entering this information
Other medications (PRN)	Please refer to your system guidelines when entering this information
Growth factor	Please refer to your system guidelines when entering this information
Hydration	**Mirvetuximab is only compatible with D5.** Please refer to your system guidelines when entering this information
Labs	Please refer to your system guidelines when entering this information

D5=5% dextrose; PRN=as needed.

ELAHERE Clinical Specifications Order Set Considerations (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Additional Information (cont'd)

Renal impairment	See Renal Impairment, section 8.6 of the **Prescribing Information**
Hepatic impairment	See Hepatic Impairment, section 8.7 of the **Prescribing Information**
Use in specific populations	See Use in Specific Populations, section 8 of the **Prescribing Information**
Supportive care	Please refer to your system guidelines when entering this information (consider antiemetics, eye drops, etc)
Pregnancy	See Use in Specific Populations, section 8.1 of the **Prescribing Information**

ELAHERE is supplied as

Carton contents	NDC
1 single-dose vial containing 100 mg of mirvetuximab soravtansine-gynx in 20 mL (5 mg/mL)	72903–853–01

General Instructions

Order sets are commonly used in the management of oncology patients. After initial release, order sets may benefit from a clinical update. The optimization of order sets is a common process and provides an opportunity to incorporate treatment updates. Order sets are typically modified at the system level to help reduce practice variation.

Typically, a practice will conduct a clinical review process to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing order set optimization requests prior to implementation.

Regimen Name

ELAHERE (mirvetuximab soravtansine-gynx) 6 mg/kg AIBW every 3 weeks

Regimen Description

ELAHERE (mirvetuximab soravtansine-gynx) 6 mg/kg AIBW every 3 weeks

Indication/Disease

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

References

ELAHERE (mirvetuximab soravtansine-gynx) Prescribing Information: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**

Regimen Keywords

ELAHERE, mirvetuximab, epithelial ovarian, fallopian tube, or primary peritoneal cancer

Treatment Calendar

ELAHERE (mirvetuximab soravtansine-gynx) 6 mg/kg AIBW every 3 weeks

	Cycle (21 days)	**Until disease progression or unacceptable toxicity**
	Day	**1**
Component	**Dosing**	
ELAHERE	6 mg/kg AIBW	Day 1 only

AIBW Calculation – AdjBW (Also referred to as Adjusted Body Weight. Use the Adjusted Body Weight as an alternative as it may already be available in the EHR):

AIBW using the following formula:

AIBW = Ideal Body Weight (IBW [kg]) + 0.4 × (Actual weight [kg] – IBW)

Female IBW (kg) = 0.9 × height (cm) – 92

Treatment Conditions

Select patients for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer with ELAHERE based on the presence of FRα tumor expression using an FDA-approved test.

Information on FDA-approved tests for the measurement of FRα tumor expression is available at **http://www.fda.gov/CompanionDiagnostics**

FRα Test

Confirm the FRα test is available in the lab catalog of the health system so it can be ordered. If the FRα test is not available, add the test as a procedure order according to the health system preferences and standard EHR conventions. Consider adding any additional information as desired (LOINC codes and charge/billing information).

FRα Testing

Procedural type	Code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

The FRα test can be evaluated at these 4 participating lab partners:

- Labcorp
- NeoGenomics
- Caris Life Sciences
- Aurora

ELAHERE Premedications and Required Eye Care

Premedication

Administer the premedications in Table 1 prior to each infusion of ELAHERE for prevention of infusion-related reactions (IRRs), nausea, and vomiting.

Table 1: Premedication Prior to Each ELAHERE Infusion

Premedication	Route of administration	Examples (or equivalent)	Administration time prior to ELAHERE infusion
Corticosteroid	Intravenous	Dexamethasone 10 mg	At least 30 minutes prior
Antihistamine	Oral or intravenous	Diphenhydramine 25 mg to 50 mg	
Antipyretic	Oral or intravenous	Acetaminophen 325 mg to 650 mg	
Antiemetic	Oral or intravenous	5-HT_3 serotonin receptor antagonist or appropriate alternatives	Before each dose and thereafter as needed

Consider additional premedications including corticosteroids the day prior to ELAHERE administration for patients who experienced IRRs.

Ophthalmic Exams and Premedication

Ophthalmic exam: Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.

Ophthalmic Topical Steroids: The use of ophthalmic topical steroids is recommended. The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer one drop of ophthalmic topical steroids in each eye 6 times daily starting the day prior to each infusion until day 4; then administer one drop in each eye 4 times daily for days 5–8 of each cycle of ELAHERE *[see Warnings and Precautions (5.1)]*.

Lubricating Eye Drops: The use of lubricating eye drops at least four times daily and as needed is recommended during treatment with ELAHERE. Instruct patients to use lubricating eye drops and advise to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops *[see Warnings and Precautions (5.1)]*.

General Instructions (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

ELAHERE Monitoring and Hold Parameters

WARNING: OCULAR TOXICITY

- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

Dose Modifications for Adverse Reactions

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
Keratitis/Keratopathy *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Nonconfluent superficial keratitis	Monitor.
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected visual acuity	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction.
	Corneal ulcer or stromal opacity or best corrected distance visual acuity 20/200 or worse	Withhold until improved or resolved, then reduce by one dose level.
	Corneal perforation	Permanently discontinue.
Uveitis *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Grade 1/Rare cell in anterior chamber	Monitor.
	Grade 2/1–2+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then maintain dose at same dose level.
	Grade 3/3+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then reduce dose by one dose level.
	Grade 4/Hypopyon	Permanently discontinue.
Pneumonitis *[see Warnings and Precautions (5.2) and Adverse Reactions (6.1)]*	Grade 1	Monitor.
	Grade 2	Withhold until Grade 1 or less, then maintain at same dose level or consider dose reduction.
	Grade 3 or 4	Permanently discontinue.
Peripheral Neuropathy *[see Warnings and Precautions (5.3) and Adverse Reactions (6.1)]*	Grade 2	Withhold until Grade 1 or less, then reduce by one dose level.
	Grade 3 or 4	Permanently discontinue.

*Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

General Instructions (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

ELAHERE Monitoring and Hold Parameters (cont'd)

Dose Modifications for Adverse Reactions (cont'd)

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
Infusion-Related Reactions/ Hypersensitivity *[see Adverse Reactions (6.1)]*	Grade 1	Maintain infusion rate.
	Grade 2	• Interrupt infusion and administer supportive treatment. • After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed *[see Dosage and Administration (2.5)]*. • Administer additional premedication for future cycles *[see Dosage and Administration (2.3)]*.
	Grade 3 or 4	• Immediately stop infusion and administer supportive treatment. • Advise patient to seek emergency treatment and immediately notify their healthcare provider if the infusion-related symptoms recur. • Permanently discontinue.
Hematological *[see Adverse Reactions (6.1)]*	Grade 3 or 4	Withhold until Grade 1 or less, then resume at one lower dose level.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	Withhold until Grade 1 or less, then resume at one lower dose level.
	Grade 4	Permanently discontinue.

Recommended Dose Reduction Schedule (adjust the schedule of administration to maintain a 3-week interval between doses)

	ELAHERE Dose Levels
First Dose Reduction	5 mg/kg AIBW once every 3 weeks (21-day cycle)
Second Dose Reduction	4 mg/kg AIBW once every 3 weeks (21-day cycle)†

ELAHERE Warnings, Precautions, and Adverse Reactions

- Consider adding the following information:
  - See section 5 of the ELAHERE **Prescribing Information** for Warnings and Precautions (Ocular Disorders, Pneumonitis, Peripheral Neuropathy, and Embryo-Fetal Toxicity)
  - See section 6 of the ELAHERE **Prescribing Information** for Adverse Reactions (Clinical Trials Experience)

*Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.
†Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.

Notes

- The Customer (ie, physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each EHR system may vary. AbbVie Inc. shall not be responsible for revising the implementation instructions it provides to any customer if the Customer modifies or changes its software or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by AbbVie Inc.
- While AbbVie Inc. tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and AbbVie Inc. shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and AbbVie Inc. shall have no liability thereto
- The instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of AbbVie Inc. and/or its affiliates

Please see Important Safety Information for ELAHERE, including Boxed Warning on pages 3-4, and click to access full Prescribing Information.

Reference: ELAHERE® (mirvetuximab soravtansine-gynx). Prescribing Information. Waltham, MA: AbbVie Inc.; 2024.