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injection 100 mg

Instructions for Patient

Instructions for Eye Care Provider

Today's date: __/__/____

Ocular Assessment Form

This is an optional tool to help support eye care for patients prescribed ELAHERE

ONCOLOGIST	PATIENT
Name	Name
Facility	Date of birth
Phone	Patient ID
Fax/email	Diagnosis (*ICD-10* code)

Please select the appropriate option:

○ Baseline exam ○ Scheduled follow-up exam ○ Follow-up due to patient-reported symptoms

Note: Premedication with ophthalmic topical steroids is recommended as part of treatment with ELAHERE, as outlined on the back page of this form (*see Proactive Management of Ocular Events*). Please coordinate prescription of eye drops with the treating oncologist.[1]

Symptom Assessment

○ Patient reports the following new or ongoing ocular symptom(s): ○ No symptoms reported

_____

Visual Acuity[1]

	Baseline exam		Current exam	
	Right eye	**Left eye**	**Right eye**	**Left eye**
Best-corrected distance visual acuity	20/	20/	20/	20/
Entering distance visual acuity Were corrective lenses worn during the assessment? ○ Yes ○ No	20/	20/	20/	20/

Ophthalmic Exam[1]

○ No abnormal findings

Finding	Severity of finding[a]	Right eye	Left eye	Eye Care Provider Action	For oncologist prescribing ELAHERE: recommended dosage modifications for adverse reactions[1]
Keratitis/ keratopathy[b]	Nonconfluent superficial keratitis	○ Yes	○ Yes	Monitor	Monitor
	Confluent superficial keratitis	○ Yes	○ Yes	If yes for either eye, notify prescribing oncologist	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction
	Cornea epithelial defect	○ Yes	○ Yes		
	3-Line or more loss in best-corrected visual acuity	○ Yes	○ Yes		
	Corneal ulcer	○ Yes	○ Yes		Withhold until improved or resolved, then reduce by one dose level
	Stromal opacity	○ Yes	○ Yes		
	Best-corrected distance visual acuity of 20/200 or worse	○ Yes	○ Yes		
	Corneal perforation	○ Yes	○ Yes		Permanently discontinue
Uveitis	Grade 1: rare cell in anterior chamber	○ Yes	○ Yes	Monitor	Monitor
	Grade 2: 1-2+ cell or flare in anterior chamber	○ Yes	○ Yes	If yes for either eye, notify prescribing oncologist	Withhold until Grade 1 or less, then maintain dose at same dose level
	Grade 3: 3+ cell or flare in anterior chamber	○ Yes	○ Yes		Withhold until Grade 1 or less, then reduce dose by one dose level
	Grade 4: hypopyon	○ Yes	○ Yes		Permanently discontinue

[a]Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.[1]
[b]Superficial punctate keratitis is defined as any corneal epithelial disturbance of dotlike morphology. Confluence refers to superficial keratitis that has coalesced into patchy areas of staining. Epithelial defect refers to focal areas of non-punctate epithelial loss. Corneal ulcer refers to epithelial defect with stromal excavation.[2-5]

Additional Information	Eye Care Provider *(Name and Contact Information)*

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Ocular Management

Your patient is being referred by their oncologist for an ophthalmic exam as they have been prescribed ELAHERE, which has the potential to cause ocular side effects.[1]

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.**

Components of an Ocular Exam (*please see Instructions for Eye Care Provider for the ocular exam schedule*)

Symptom Assessment[1]
Inquire about any new or worsening ocular symptoms (eg, vision impairments, dry eye, photophobia, eye pain), and treat as appropriate

Visual Acuity[1]
Measure best-corrected visual acuity at baseline, and use it as a comparison during follow-up examinations to help determine whether changes have occurred

Slit Lamp Exam[1]
Assess corneal health (eg, keratopathy, superficial punctate keratitis) before and throughout treatment with ELAHERE[a]

[a]Note preexisting signs and symptoms of ocular surface disease.[6]

Proactive Management of Ocular Events

Patients should receive a baseline ophthalmic exam from an ophthalmologist or optometrist before treatment initiation and follow-up exams during every other cycle for the first 8 cycles, and as clinically indicated[1]

Tell patients to avoid use of contact lenses, unless they are medically necessary[1]

Use of preservative-free lubricating eye drops at least 4 times daily and as needed is recommended during treatment with ELAHERE[1,7,b]

- Advise patients to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops

Use of ophthalmic topical corticosteroids is recommended[1]

- The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp
- Patients should administer 1 drop of ophthalmic topical steroid in each eye 6 times daily starting the day before each infusion of ELAHERE until day 4
- Patients should administer 1 drop in each eye 4 times daily on days 5 to 8 of each cycle of ELAHERE

[b]Preservative-free is not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.[7]

Questions:

For patient-specific questions, please reach out to the prescribing oncologist

For additional questions or to report adverse events, call:
1-833-ELAHERE (1-833-352-4373)
Monday to Friday, 9 AM to 8 PM eastern time (EST)

Visit the eye care section of www.ELAHEREhcp.com

Please see Important Safety Information on pages 3 and 4, and click here for full Prescribing Information, including BOXED WARNING.

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Important Safety Information

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.

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.

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Important Safety Information
(continued)

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.**

References: 1. ELAHERE. Package insert. AbbVie Inc.; 2024. **2.** Bunya VY. Superficial punctate keratitis. Merck Manuals: Professional Version. Accessed August 8, 2024. https://www.merckmanuals.com/professional/eye-disorders/corneal-disorders/superficial-punctate-keratitis. **3.** Rodriguez JD, et al. *Invest Ophthalmol Vis Sci.* 2015;56(4):2340-2347. **4.** Corneal epithelial defect. American Academy of Ophthalmology. Accessed August 8, 2024. https://eyewiki.org/Corneal_Epithelial_Defect. **5.** Bunya VY. Corneal ulcer. Merck Manuals: Professional Version. Accessed August 8, 2024. https://www.merckmanuals.com/professional/eye-disorders/corneal-disorders/corneal-ulcer. **6.** Data on file. ImmunoGen, Inc. **7.** Moore KN, et al. *N Engl J Med.* 2023;389(23):2162-2174.

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Instructions for Patient

Your oncologist is referring you to an eye care provider to care for your eyes during your treatment with ELAHERE. ELAHERE may cause eye-related adverse events.

USE

What is ELAHERE?

ELAHERE is a prescription medicine used to treat adults with folate receptor-alpha positive ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who:

- have not responded to or are no longer responding to treatment with platinum-based chemotherapy
  and
- have received 1 to 3 prior types of chemotherapy.

Your healthcare provider will perform a test to make sure that ELAHERE is right for you.

It is not known if ELAHERE is safe and effective in children.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ELAHERE?

ELAHERE can cause serious side effects, including:

Eye problems. Eye problems are common with ELAHERE and can also be severe. Tell your healthcare provider right away if you develop any eye problems during treatment with ELAHERE, including blurred vision, dry eyes, sensitivity to light, eye pain, eye redness, or new or worsening vision changes.

- Your healthcare provider will send you to see an eye care professional to check your eyes before you start treatment with ELAHERE, during treatment with ELAHERE, and as needed for any worsening signs and symptoms of eye problems.
- Your healthcare provider will prescribe steroid eye drops and lubricating eye drops before you start and during your treatment with ELAHERE. You should use eye drops as directed by your healthcare provider.
- Do not wear contact lenses throughout your treatment with ELAHERE unless you are told to use them by your healthcare provider.

Please consider the following eye care regimen for ELAHERE:

1. Before leaving your oncologist's office, make sure the top section of the included Ocular Assessment Form is completed
2. As soon as possible, make an appointment with an eye care provider *(ophthalmologist or optometrist, either can perform the needed exams and monitoring)*
   a. If you don't have an eye care provider or one is not recommended by your oncologist, you can find an eye care provider by going to ELAHERE.com or scanning the QR code at the bottom of this page
   b. Schedule your eye care appointment for a date that is before your first treatment with ELAHERE, which is on:
   __/__/____
3. When contacting your eye care provider, state the following information:
   a. I am a **patient with ovarian cancer,** and I need an eye appointment as soon as possible **before I start treatment with ELAHERE** *(contact a different eye care provider if you can't get an appointment before starting ELAHERE)*
   b. I need an eye exam that includes a **visual acuity and slit lamp exam,** and I will **bring an Ocular Assessment Form with me for the eye care provider to complete**
   c. After my first appointment, I will need **additional eye exams** to monitor for eye side effects while I am on ELAHERE
4. At your eye care appointment, before leaving your eye care provider's office, schedule your next appointment about **6 weeks** after your first appointment *(this second appointment is to check your eyes after your second treatment with ELAHERE)*

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Please see Important Safety Information on the next page, and click here for full Prescribing Information, including BOXED WARNING.

Scan this QR code for additional eye care guidance or help finding an eye care provider

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before receiving ELAHERE?

Tell your healthcare provider about all of your medical conditions, including if you:

- have vision or eye problems.
- have numbness or tingling in your hands or feet.
- have liver problems.
- are pregnant or plan to become pregnant. ELAHERE can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ELAHERE.

  Patients who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with ELAHERE.
  - You should use an effective birth control (contraception) during treatment and for 7 months after your last dose of ELAHERE.
- are breastfeeding or plan to breastfeed. It is not known if ELAHERE passes into your breast milk. Do not breastfeed during treatment and for 1 month after your last dose of ELAHERE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking certain other medicines during treatment with ELAHERE may cause side effects.

What are the possible side effects of ELAHERE?

ELAHERE can cause serious side effects, including:

- **Eye problems.** Eye problems are common with ELAHERE and can also be severe. Tell your healthcare provider right away if you develop any eye problems during treatment with ELAHERE, including blurred vision, dry eyes, sensitivity to light, eye pain, eye redness, or new or worsening vision changes.
- **Lung problems (pneumonitis).** ELAHERE can cause severe or life-threatening inflammation of the lungs that may lead to death. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, cough, or chest pain.
- **Peripheral neuropathy**. Nerve problems called peripheral neuropathy are common during treatment with ELAHERE and can also be severe. Your healthcare provider will monitor you for signs and symptoms of nerve problems. Tell your healthcare provider if you get new or worsening numbness, tingling, burning sensation or pain in your hands or feet or muscle weakness.

The most common side effects and abnormal labs of ELAHERE include:

- increased liver enzymes in the blood
- feeling tired
- blurred vision
- nausea
- diarrhea
- stomach-area (abdominal) pain
- changes in the cornea (part of the eye)
- peripheral neuropathy
- muscle, bone, or joint pain
- decreased red or white blood cell counts
- decreased platelets
- decreased magnesium level in the blood
- dry eye
- constipation
- vomiting
- decreased albumin level in the blood
- decreased appetite

Your healthcare provider may change your dose of ELAHERE, delay treatment, or completely stop treatment if you have certain side effects.

These are not all of the possible side effects of ELAHERE. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Full Prescribing Information, including BOXED WARNING and Medication Guide.

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Instructions for Eye Care Provider

This patient has been referred to you to manage her eye care while she is on a cancer treatment that may cause ocular adverse events, including, but not limited to, changes to the corneal epithelium (keratopathy), dry eye sensation, and/or changes in vision

Please consider the following eye care regimen for ELAHERE

1. Perform an ophthalmic exam to establish a baseline **before the start of treatment** with ELAHERE. This should include **best-corrected visual acuity and slit lamp exam**

2. After this baseline visit, work with the patient to schedule **3 additional ophthalmic monitoring visits at ~6-week intervals** (timed to every other ELAHERE infusion for the first 8 cycles). ELAHERE is administered once every 3 weeks

   If ocular symptoms develop, additional appointments may be needed to evaluate and manage the symptoms, as clinically indicated

3. **Fill out the included Ocular Assessment Form** to communicate the findings with the oncologist

   The oncologist will use this information to determine whether to modify the patient's treatment (delay, reduce, or discontinue dosing). You may include additional pertinent information in the provided box on the form

   If you need additional guidance on the steps you need to take, and access to resources such as the Ocular Billing and Coding Guide, please go to ELAHEREhcp.com or scan the QR code at the bottom of this page

4. Refer to the included **Ocular Management page** for additional information on **proactive ocular management strategies** for patients receiving treatment with ELAHERE

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If you need additional guidance on ocular assessment for patients receiving ELAHERE, please visit ELAHEREhcp.com