

Ocular Assessment Form

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

Today's date: ___/___/_____



ONCOLOGIST

Name
Facility
Phone
Fax/email

PATIENT

Name
Date of birth
Patient ID
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 next page of this form (see *Schedule for Eye Drops*). Please coordinate the prescribing of eye drops with the referring 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 Exam¹

☐ 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 referring oncologist	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction
	Cornea epithelial defect	☐ Yes	☐ Yes		Withhold until improved or resolved, then reduce by one dose level
	3-Line or more loss in best-corrected visual acuity	☐ Yes	☐ Yes		
	Corneal ulcer	☐ Yes	☐ Yes		
	Stromal opacity	☐ Yes	☐ Yes		Permanently discontinue
	Best-corrected distance visual acuity of 20/200 or worse	☐ Yes	☐ Yes		
Uveitis	Corneal perforation	☐ Yes	☐ Yes		
	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 referring 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

^aUnless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.¹

^bSuperficial 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. Cornea epithelial defect refers to focal areas of non-punctate epithelial loss. Corneal ulcer refers to epithelial defect with stromal excavation.²⁻⁷

Additional Information

Eye Care Provider (Name and Contact Information)

Please see Important Safety Information throughout.

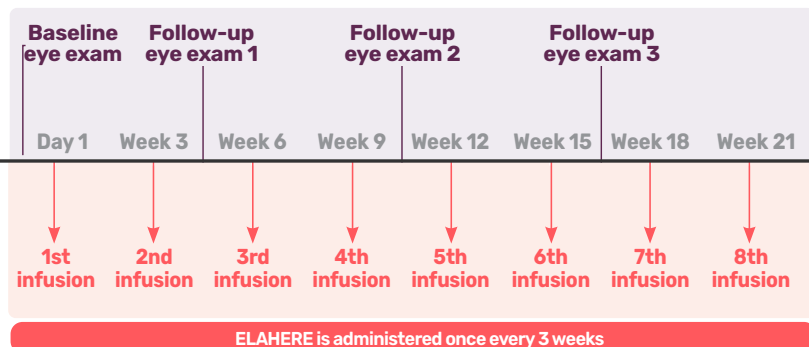
Please see **full Prescribing Information**, including **BOXED WARNING**, or visit https://www.rxabbvie.com/pdf/elahere_pi.pdf

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

Proactive Management of Ocular Events¹



- Patients should receive a baseline ophthalmic exam from an ophthalmologist or optometrist before treatment initiation
- After the baseline exam, 3 additional follow-up exams should be scheduled at ~6-week intervals (timed prior to every other ELAHERE infusion for the first 8 cycles)



Schedule for Eye Drops¹



- The use of ophthalmic topical steroids and preservative-free lubricating eye drops^a is recommended
- The initial prescription and renewals of any corticosteroid medication should be made only after a slit lamp exam

Steroid eye drops¹

Day before infusion → Day 4

1 drop per eye | 6x daily

Day 5 → Day 8

1 drop per eye | 4x daily

Lubricating eye drops¹

Day 1 → Treatment duration

1 drop per eye | at least 4x daily

Wait at least 10 minutes after administration of the ophthalmic topical steroid

Tell your patients to avoid the use of contact lenses during treatment with ELAHERE¹

^aPreservative-free is not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.^{1,8}

INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FR α) 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

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.**

Questions:



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



For additional questions or to report adverse events, call 1-800-633-9100
Monday to Friday, 9 AM to 8 PM eastern time



Visit the eye care section of
www.ELAHEREhcp.com

Please see Important Safety Information throughout.

Please see full Prescribing Information, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/elahere_pi.pdf



This patient has been referred to you to manage their eye care while on a cancer treatment. ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis¹

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 the following¹:



Symptom Assessment

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



Visual Acuity

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

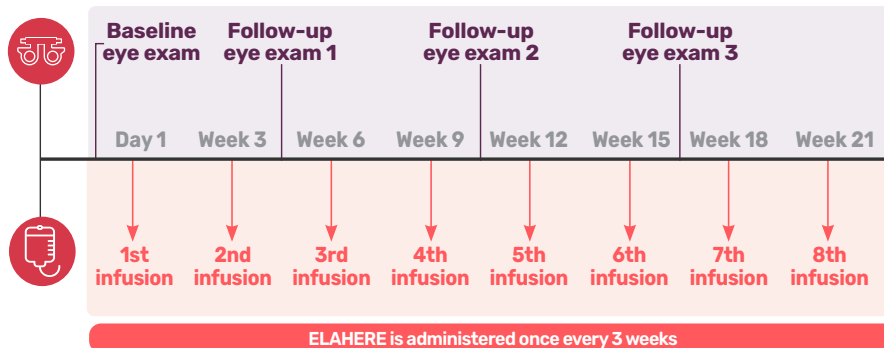
Assess corneal health (eg, keratopathy, superficial punctate keratitis) before and throughout treatment with ELAHERE^a

^aNote preexisting signs and symptoms of ocular surface disease.⁹

2. After this baseline visit, work with the patient to schedule **3 additional ophthalmic monitoring visits at ~6-week intervals** (timed prior to every other ELAHERE infusion for the first 8 cycles)¹

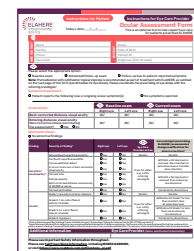
If ocular symptoms develop, additional appointments may be needed to evaluate and manage the symptoms, as clinically indicated¹

ELAHERE eye exam schedule¹



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

- The oncologist will use this information to determine whether to modify the patient's treatment (delay, reduce, or discontinue dosing)¹
- 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](https://www.ELAHEREhcp.com) or scan the QR code at the bottom of this page



4. Reiterate to patients the importance of adhering to the **Schedule for Eye Drops**, which includes the use of **2 types of eye drops**, while receiving treatment with ELAHERE¹

Premedication with ophthalmic topical steroids and use of preservative-free lubricating eye drops^b are recommended as part of treatment with ELAHERE.¹ Please coordinate the prescribing of eye drops with the referring oncologist

Steroid eye drops¹

Day before infusion → Day 4

1 drop per eye | 6x daily

Day 5 → Day 8

1 drop per eye | 4x daily

Lubricating eye drops¹

Day 1 → Treatment duration

1 drop per eye | at least 4x daily

Tell your patients to avoid the use of contact lenses during treatment with ELAHERE¹

Wait at least 10 minutes after administration of the ophthalmic topical steroid

^bPreservative-free is not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.^{1,8}

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If you need additional guidance on ocular assessment for patients receiving ELAHERE, please visit [ELAHEREhcp.com](https://www.ELAHEREhcp.com)

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 ($\geq 5\%$) 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 $\leq$ 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 Important Safety Information throughout.

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WARNINGS and PRECAUTIONS (continued)

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 ($\geq 20\%$) 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 Important Safety Information throughout.

Please see accompanying full Prescribing Information, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/elahere_pi.pdf

References: **1.** Elahere. Prescribing information. AbbVie Inc.; 2025. **2.** Bunya VY. Superficial punctate keratitis. Merck Manuals: Professional Version. Accessed June 23, 2025. <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 June 23, 2025. https://eyewiki.org/Corneal_Epithelial_Defect. **5.** Bunya VY. Corneal ulcer. Merck Manuals: Professional Version. Accessed June 23, 2025. <https://www.merckmanuals.com/professional/eye-disorders/corneal-disorders/corneal-ulcer>. **6.** Galor A. In: Mannis MJ, Holland EJ, eds. *Cornea*. 5th ed. Elsevier Inc; 2022:81-89. **7.** Nishida T. In: Mannis MJ, Holland EJ, eds. *Cornea*. 5th ed. Elsevier Inc; 2022:1-22. **8.** Moore KN, et al. *N Engl J Med*. 2023;389(23):2162-2174. **9.** Data on File. AbbVie, Inc. ABVRRTI80483.



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.

Please consider the following eye care tips while you receive ELAHERE treatment:

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 **before your first treatment with ELAHERE**, 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](https://www.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 **3 additional eye exams at 6-week intervals**, and as clinically indicated to monitor for eye side effects while I am on ELAHERE
4. At your eye care appointment, before leaving the office, schedule your next appointment about **6 weeks** after your current appointment (*these ongoing appointments are to check your eyes during your treatment with ELAHERE*)
5. Your eye care provider should call or fax the referring oncologist with your eye care findings. They may also provide you with a copy of the Ocular Assessment Form to bring to your next oncology appointment

USE and IMPORTANT SAFETY INFORMATION

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.

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 see Important Safety Information throughout.

Please see **Consumer Brief Summary**, or visit

https://www.rxabbvie.com/pdf/elaHERE_pi.pdf 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.

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