

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ELAHERE**®

#### Mirvetuximab soravtansine for injection

This patient medication information is written for the person who will be taking **ELAHERE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ELAHERE**, talk to a healthcare professional.

#### Serious warnings and precautions box

- Eye Problems are common with ELAHERE and can be severe. Tell your health professional 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.

#### What ELAHERE is used for:

- ELAHERE is a cancer medicine that contains the active substance mirvetuximab soravtansine.
- ELAHERE is used to treat adults with ovarian cancer, fallopian tube (one of two long, slender tubes that connect the ovaries to the womb) cancer, or primary peritoneal cancer (cancer that forms in the tissue that lines the abdominal wall and covers organs in the abdomen, and has not spread there from another part of the body). It is used in patients whose cancer cells have a protein on the surface known as folate receptor-alpha (FR $\alpha$ ), and who have previously not responded to or are no longer responding to treatment with 'platinum-based' chemotherapy, and who have already received one to three prior treatments.

Your health professional will perform a test to make sure that ELAHERE is right for you. This test is done on tissue from your tumour. If you have tissue available from a previous surgery or biopsy, this archived material will be tested. If you do not have prior tissue, this test will require a tumour biopsy.

#### How ELAHERE works:

The active substance in ELAHERE, mirvetuximab soravtansine, is made up of two parts. One part is a monoclonal antibody that attaches specifically to cancer cells that have FR $\alpha$  on their surface (FR $\alpha$ -positive). The second part, DM4, is attached to the antibody. After ELAHERE enters the cells, DM4 is released from the antibody. DM4 then stops the normal growth process of the cancer cells. This can help kill cancer cells and stop the spread of the disease.

#### The ingredients in ELAHERE are:

Medicinal ingredient: Mirvetuximab soravtansine

Non-medicinal ingredients: glacial acetic acid, polysorbate 20, sodium acetate, sucrose, and water for injection

**ELAHERE comes in the following dosage form(s):**

ELAHERE is available as single-use vials: 100 mg/20 mL (5mg/mL).

**Do not use ELAHERE if:**

- you are allergic to mirvetuximab soravtansine or any of the other ingredients of this medicine (listed under “**The ingredients in ELAHERE are**”). Talk to your doctor before you are given ELAHERE if you are not sure.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ELAHERE. Talk about any health conditions or problems you may have, including if you:**

- have vision or eye problems requiring active treatment or monitoring. Do not wear contact lenses throughout your treatment with ELAHERE unless you are told to use them by your health professional.
- have nerve damage in the arms and legs. Symptoms may include numbness, tingling, or weakness.
- are pregnant or plan to become pregnant. ELAHERE could harm an unborn baby if taken during pregnancy.
- are breastfeeding or plan to breastfeed.
- have liver problems.

**Other warnings you should know about:**Eye problems

Eye Problems are common with ELAHERE and can be severe (see “Serious warnings and precautions box” for further information). Your healthcare professional 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 professional will prescribe lubricating eye drops before and during your treatment with ELAHERE. If you experience symptoms of eye problems, steroid eye drops may also be prescribed as needed. You should use eye drops as directed by your healthcare professional.

Inflammation in the lungs

Severe, life-threatening scarring of the lungs (interstitial lung disease), including inflammation of the lungs can occur in patients treated with ELAHERE. Your doctor will monitor you for signs of lung inflammation. Tell your doctor if you develop coughing, wheezing, chest pain or difficulty breathing.

Nerve damage in the arms and legs

Signs and symptoms of nerve damage may include pins and needles sensation, tingling or a burning sensation, pain due to nerve damage, muscle weakness, and an unpleasant, abnormal sense of touch, particularly in your arms or legs.

Infusion-related reactions

Infusion-related reactions have occurred with ELAHERE. To minimize the risk of these reactions, your doctor will give you some medicines, see “Medicines given before infusion” section. In case of severe reactions, your doctor will stop the infusion immediately and you will be given supportive treatment.

### Pregnancy, Contraception, Breast-feeding and fertility

- ELAHERE can harm your unborn baby. Tell your health professional right away if you become pregnant or think you may be pregnant during treatment with ELAHERE.
- You should use effective birth control (contraception) during treatment with ELAHERE and for 7 months after the last dose of ELAHERE.
- If you become pregnant during treatment with ELAHERE or within 7 months after stopping treatment, tell your doctor immediately.
- If you are able to become pregnant, you will be asked to take a pregnancy test before you start treatment with ELAHERE.
- You must not breast-feed during treatment with ELAHERE and for 1 month after the last dose. ELAHERE may be passed into breast milk and could potentially harm the baby.
- The effects of ELAHERE on male and female fertility are not known. Fertility problems are possible when taking this medicine.

### Driving and using machines

- ELAHERE may affect your ability to drive and use machines. If you experience blurred vision or nerve damage, causing pain, numbness or weakness in your hands, arms, or feet, do not drive, use tools, or operate machines until your symptoms are completely better.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with ELAHERE:**

- Ceritinib (cancer medicine to treat non-small cell lung cancer)
- Clarithromycin (antibiotic for treating bacterial infections)
- Cobicistat, ritonavir (antiviral medicines to treat HIV/AIDS)
- Idelalisib (cancer medicine to treat certain blood cancers)
- Itraconazole, ketoconazole, posaconazole, voriconazole (antifungal medicines to treat fungal infections)
- Nefazodone (antidepressant)
- Telithromycin (antibiotic for treating community acquired pneumonia)
- Folate-containing supplements

### **How to take ELAHERE:**

- ELAHERE will be given to you by a doctor or a nurse experienced in using cancer medicines.
- ELAHERE will be given to you by an infusion into your vein (intravenously).
- Before each dose of ELAHERE you will receive medicines to help prevent infusion-related reactions, nausea, and vomiting.
- ELAHERE is usually given over 2 to 4 hours, once every 3 weeks (21-day cycle). Your health professional will decide how many cycles you need.

### Medicines given before infusion

Your doctor will give you the following medicines about 30 minutes before each infusion:

- Corticosteroids (for inflammation) such as dexamethasone
- Antihistamines (for allergies) such as diphenhydramine
- Antipyretics (to reduce fever) such as acetaminophen

You will also be given corticosteroids the day before your infusion if you have previously suffered from infusion-related reactions.

Your doctor will also give you a medicine to reduce nausea and vomiting before each dose and thereafter as needed.

### **Usual dose:**

The recommended dose of ELAHERE is 6 mg/kg adjusted to your ideal body weight. Your doctor will calculate your dose.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much ELAHERE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

### **Missed dose:**

If you miss an appointment to have ELAHERE administered, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

### **Possible side effects from using ELAHERE**

These are not all the possible side effects you may have when taking ELAHERE. If you experience any side effects not listed here, tell your healthcare professional.

Very common (may affect more than 1 in 10 people):

- tiredness
- belly (abdominal) pain
- muscle, bone, and joint pain
- diarrhea
- constipation
- feeling sick (nausea)
- vomiting
- loss of appetite
- headache
- low levels of neutrophils, a type of white blood cell that fights infection (neutropenia)
- low levels of magnesium in the blood (hypomagnesemia)
- low levels of potassium in the blood (hypokalemia)
- blood tests showing an increase in liver enzymes

Common (may affect up to 1 in 10 people):

- low red blood cell counts which can cause tiredness and pale skin (anemia)
- low blood platelet counts which can lead to bleeding and bruising (thrombocytopenia)
- weight loss
- dehydration
- blood tests showing an increase in liver enzymes
- high blood bilirubin levels (hyperbilirubinemia) which may cause yellowing of skin or eyes

**Serious side effects and what to do about them**

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
<b>Very common</b>			
<b>Eye disorders</b> (Eye problems): damage to the cornea, the transparent layer of the eye (keratopathy), clouding of the eye lens (cataract), blurred vision, sensitivity to light (photophobia), eye pain, and dry eye		√	
<b>Nervous system disorders</b> (Nerve damage in the arms and legs): pins and needles sensation, tingling or a burning sensation, pain due to nerve damage, muscle weakness, and an unpleasant, abnormal sense of touch, particularly in your arms or legs		√	
<b>Common</b>			
<b>Respiratory, thoracic and mediastinal disorders</b> (Inflammation in the lungs): difficulty breathing, cough, low levels of oxygen resulting in confusion, restlessness, rapid heart rate, bluish skin, or scarring of the lungs which would be picked up from an X-ray		√	

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
<b>Procedural complications</b> (Infusion-related reactions/hypersensitivity): low blood pressure, fever, chills, nausea, vomiting, headache, lightheadedness, difficulty breathing, wheezing, rash, flushing, swelling of the face or around the eye, sneezing, itchiness, muscle or joint pain		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

ELAHERE will be stored by the doctor, nurse, or pharmacist at the hospital or clinic.

Store and transport refrigerated (2 to 8°C).

Keep the vial in the original carton in order to protect from light.

Do not freeze. Do not shake.

#### If you want more information about ELAHERE

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.abbvie.ca](http://www.abbvie.ca)); or by 1-888-704-8271.

- Educational materials for patients and caregivers related to the product use and safety information are available through the manufacturer.

This leaflet was prepared by AbbVie Corporation.

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