

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I being treated with Elahere?

Elahere contains the active ingredient mirvetuximab soravtansine. Elahere is used to treat adults with folate receptor-alpha (FR $\alpha$ ) positive ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who are no longer responding to treatment with platinum-based chemotherapy and who have received 1 to 3 prior lines of chemotherapy.

For more information, see Section [1. Why am I being treated with Elahere?](#) in the full CMI.

### 2. What should I know before I am given Elahere?

Do not use if you have ever had an allergic reaction to Elahere or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Elahere?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Elahere and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Elahere given?

You will receive Elahere by an infusion (drip) into your vein (intravenously) over 2 to 4 hours, once every 3 weeks (this is known as a 21-day treatment cycle).

More instructions can be found in Section [4. How is Elahere given?](#) in the full CMI.

### 5. What should I know while I am treated with Elahere?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist, pharmacist or eye care professional you visit that you are being treated with Elahere.</li><li>Before each treatment cycle, it is important that you tell your doctor or eye care professional if you have any new or worsening eye problems.</li><li>Call your doctor straight away if you experience any signs and symptoms of problems with your eyes (i.e. blurred vision, dry eyes, sensitivity to light, eye pain, or new or worsening vision changes), inflammation in the lungs, nerve damage in your arms and legs and infusion-related reactions / hypersensitivity. For more information, see Section <a href="#">2 What should I know before I am given Elahere?</a> in the full CMI.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not miss any of your scheduled appointments relating to your treatment with Elahere.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Elahere may affect your ability to drive and use machines. If you feel any symptoms that may affect your ability to drive, do not drive, or use machines until the symptoms stops.</li></ul>

For more information, see Section [5. What should I know while I am treated with Elahere?](#) in the full CMI.

### 6. Are there any side effects?

The more serious side effects can include signs and symptoms of problems with your eyes, inflammation in the lungs, nerve damage in your arms and legs and infusion-related reactions / hypersensitivity.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# ELAHERE<sup>®</sup> (el-a-hear)

Active ingredient(s): mirvetuximab soravtansine (mer-veh-tuk-sih-mab soh-rav-tan-seen)

## Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with Elahere. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with Elahere.**

Where to find information in this leaflet:

- [1. Why am I using Elahere?](#)
- [2. What should I know before I use Elahere?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Elahere?](#)
- [5. What should I know while using Elahere?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being treated with Elahere?

**Elahere contains the active ingredient mirvetuximab soravtansine.**

Elahere is a type of medicine called an antibody drug conjugate. It is made up of an antibody attached to a cancer medicine called DM4. The antibody is a protein that attaches to another protein on cancer cells known as folate receptor-alpha (FR $\alpha$ ). When this happens, Elahere enters the cancer cells and releases the DM4, which kills cancer cells by stopping their normal growth process.

**Elahere is used to treat adults with cancer of the ovary, the fallopian tubes (part of the female reproductive system that connects the ovaries to the uterus), or the peritoneum (the membrane lining the abdomen).**

Elahere is used in patients whose cancer cells test positive to FR $\alpha$ , and are no longer responding to treatment with platinum-based chemotherapy and who have received 1 to 3 prior lines of chemotherapy. This test is done on tissue from your tumour. If you have tissue available from a previous surgery or biopsy, this archived material may be used. If you do not have prior tissue, this test will require a tumour biopsy. Your doctor will ensure that you had a test to make sure Elahere is right for you.

Talk to your doctor or nurse if you have any questions about how Elahere works or why this medicine has been prescribed for you.

## 2. What should I know before I am given Elahere?

### Warnings

**Do not use Elahere if:**

- you are allergic to mirvetuximab soravtansine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have vision or eye problems requiring active treatment or monitoring
- have nerve damage in the arms and legs (symptoms may include numbness, tingling or weakness)
- are pregnant or plan to become pregnant.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#) and tell your doctor if you have any symptoms of serious side effects described.

### Eye problems

Eye problems are common with Elahere and can cause severe eye problems such as loss of vision, damage to the cornea (the transparent layer in the front of the eye), dry eyes, abnormal sensitivity of the eyes to light or eye pain.

Tell your doctor right away if you develop any eye problems during treatment with Elahere, including blurred vision, dry eyes, sensitivity to light, eye pain, or new or worsening vision changes.

You will see an eye care professional before starting treatment. It is important that you report any new or worsening eye problems before the start of each treatment cycle. You should use eye drops to moisturise the eyes during treatment. If you develop certain side effects affecting the eyes, your doctor may prescribe additional eye drops containing corticosteroids. Do not wear contact lenses throughout your treatment with Elahere unless you are told to use them by a doctor.

### Inflammation in the lungs

Severe, life-threatening scarring of the lungs 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 arms and legs**

Nerve damage in arms and legs can be serious and severe and can occur when treated with Elahere. Your doctor will monitor you for signs of nerve damage.

Tell your doctor if you develop symptoms of nerve damage such as sensations like numbness, tingling, pins and needles, burning, pain, muscle weakness and distorted sense of touch in your arms or legs.

### **Infusion-related reactions**

Infusion-related reactions have occurred with Elahere. Your doctor will give you some medicines before you are given Elahere to help prevent infusion-related reactions. In case of severe reactions, your doctor will stop the infusion immediately and you will be given supportive treatment.

### **Pregnancy, Breastfeeding and Fertility**

Pregnancy must be ruled out before treatment.

If you are able to become pregnant, you will be asked to take a pregnancy test before you start treatment with Elahere.

Elahere could harm an unborn baby if taken during pregnancy because it contains a compound that can damage genes and cells that are growing rapidly. Therefore, using Elahere during pregnancy is not recommended.

**Tell your doctor immediately if you become pregnant during treatment with Elahere or within seven months after stopping treatment.**

If you are able to become pregnant, you must use an effective contraception during treatment and for 7 months after the last dose of Elahere.

You must not breast-feed during treatment with Elahere and for 1 month after the last dose. It is not known if Elahere passes into breast milk.

The effect of Elahere on female fertility is unknown. Due to how the medicine works, fertility problems are possible when taking this medicine.

It is not known if Elahere is safe and effective in children under the age of 18 years.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Taking certain other medicines during treatment with Elahere may cause side effects.

The following medicines may increase the risk of side effects of Elahere by increasing the amount of Elahere in the blood. These medicines include:

- 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)

The following medicines may decrease the amount of Elahere in the blood. These medicines include:

- phenytoin (medicine used to treat epilepsy or certain heart conditions)
- rifampicin (medicine used to treat tuberculosis and other serious infections)
- carbamazepine (medicine used to treat epilepsy to prevent convulsions, fits)

## **4. How is Elahere given?**

### **How is Elahere administered?**

Elahere will be given to you by a doctor or a nurse experienced in using cancer medicines.

Your doctor will calculate your dose based on your body weight. You will receive Elahere by an infusion (drip) into your vein (intravenously) over 2 to 4 hours, once every 3 weeks (this is known as a 21-day treatment cycle). Your doctor will decide how many cycles you need.

You may be given other medicines before you are given Elahere. This is to help prevent side effects of the treatment.

### **If you miss a dose of Elahere**

If you forget or miss your appointment, call your doctor or your treatment centre to make another appointment as soon as possible. Do not wait until your next planned visit. For the treatment to be fully effective, it is very important not to miss a dose unless recommended by your doctor.

### **If you are given more Elahere than you should have been given**

Since the infusion is given to you by your doctor or nurse, it is unlikely that you will be given too much. If you experience any side effects after being given Elahere, tell your doctor or nurse immediately.

## **5. What should I know while I am treated with Elahere?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- Experience any signs and symptoms of problems with your eyes, inflammation in the lungs, nerve damage in your arms and legs and infusion-related reactions / hypersensitivity listed in [Section 6. Are there any side effects?](#)

Remind any doctor, dentist, pharmacist or eye care professional you visit that you are being treated with Elahere.

### Things you should not do

- Do not miss any of your scheduled appointments.
- Do not wear contact lenses during treatment with Elahere, unless you are told to do so by your doctor or eye care professional.

### Eye care

An eye care professional will examine your eyes prior to starting treatment with Elahere.

- Before each treatment cycle, it is important that you tell your doctor or eye care professional if you have any new or worsening eye problems. If you develop moderate or severe eye problems during treatment, your doctor may reduce the dose of your treatment until your problems improve.
- Your doctor may adjust, withdraw or permanently stop Elahere treatment if signs and symptoms reveal any worsening problems in your eyes.

### Eye Drops

- You are recommended to use lubricating eye drops when needed throughout Elahere treatment.
- If you experience moderate or severe eye side effects your doctor may recommend that you take topical steroid eye drops.
- It is important to follow your doctor's instruction for when to take steroid eye drops, and to wait at least 15 minutes after using the topical steroid eye drops before using the lubricating eye drops.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Elahere affects you.**

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.

### Looking after your medicine

Elahere will be stored by the doctor, nurse, or pharmacist at the hospital or clinic in a refrigerator at a temperature between 2°C to 8°C.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>General</b></p> <ul style="list-style-type: none"> <li>• Tiredness</li> <li>• belly (abdominal) pain</li> <li>• pain in muscle, bone or joint</li> <li>• diarrhoea</li> <li>• constipation</li> <li>• feeling unwell/sick (nausea)</li> <li>• vomiting</li> <li>• loss of appetite</li> <li>• headache</li> <li>• weight loss</li> <li>• dehydration</li> </ul> <p><b>Shown in blood tests:</b></p> <ul style="list-style-type: none"> <li>• low levels of neutrophils, a type of white blood cell that fights infection (neutropenia)</li> <li>• low red blood cell counts which can cause tiredness and pale skin (anaemia)</li> <li>• low blood platelet counts which can lead to bleeding and bruising (thrombocytopenia)</li> <li>• high blood bilirubin levels which may cause yellowing of skin or eyes</li> <li>• showing an increase in levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT)</li> <li>• showing an increase in levels of alkaline phosphate (ALP) and gamma-glutamyl transferase (GGT)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Problems in your eye(s)</b></p> <p>Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>• eye pain</li> <li>• dry eye</li> <li>• blurred vision</li> <li>• new or worsening vision changes</li> <li>• sensitivity to light</li> <li>• clouding of the eye lens</li> <li>• damage to the cornea, the transparent layer of the eye</li> </ul> <p><b>Inflammation in the lungs</b></p> <p>Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>• difficulty breathing</li> <li>• cough</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>low levels of oxygen resulting in confusion</li> <li>restlessness</li> <li>rapid heart rate</li> <li>bluish skin</li> <li>or scarring of the lungs which would be picked up from an x-ray</li> </ul> <p><b>Nerve damage in the arms and legs</b></p> <p>Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>pins and needles sensation</li> <li>tingling or a burning sensation</li> <li>pain due to nerve damage</li> <li>muscle weakness and,</li> <li>an unpleasant, abnormal sense of touch, particularly in your arms of legs</li> </ul> <p><b>Infusion-related reactions / hypersensitivity</b></p> <p>Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>low blood pressure</li> <li>fever</li> <li>chills</li> <li>nausea</li> <li>vomiting</li> <li>headache</li> <li>light-headedness</li> <li>difficult breathing</li> <li>wheezing</li> <li>rash</li> <li>flushing</li> <li>swelling of the face or around the eye</li> <li>sneezing</li> <li>itchiness</li> <li>muscle or joint pain</li> </ul>	

**For serious side effects, your doctor may change your dose of Elahere, delay treatment or completely stop treatment if you have certain side effects.**

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Elahere contains

<b>Active ingredient (main ingredient)</b>	mirvetuximab soravtansine
<b>Other ingredients (inactive ingredients)</b>	glacial acetic acid sodium acetate sucrose polysorbate 20 water for injections

The vial stopper is NOT made with natural rubber latex.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Elahere looks like

Elahere is a sterile, preservative-free, clear to slightly opalescent, colourless solution. Elahere is supplied in a pack size of 1 single-dose vial containing 100 mg/20 mL concentrate solution for infusion (AUST R 472925).

### Who distributes Elahere

Elahere is distributed in Australia by:

AbbVie Pty Ltd  
241 O'Riordan Street  
Mascot NSW 2020  
Australia

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