

Package leaflet: Information for the patient

ELAHERE CONCENTRATE FOR SOLUTION FOR INFUSION 100MG/20ML

mirvetuximab soravtansine

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ELAHERE is and what it is used for
2. What you need to know before you are given ELAHERE
3. How you will be given ELAHERE
4. Possible side effects
5. How to store ELAHERE
6. Contents of the pack and other information

1. What ELAHERE is and what it is used for

What ELAHERE is

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 α), 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.

How ELAHERE works

The active substance in ELAHERE, mirvetuximab soravtansine, is made up of a monoclonal antibody which is attached to a cancer medicine. The monoclonal antibody is a protein that recognises and attaches to the FR α protein on the cancer cells. When this happens, mirvetuximab soravtansine enters the cancer cell and releases the cancer medicine DM4. DM4 then stops the normal growth process of the cancer cells. This can help kill cancer cells and stop the spread of the disease.

Your doctor will ensure that you have had a test confirming that you are eligible to receive ELAHERE. 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 tested. If you do not have prior tissue, this test will require a tumour biopsy.

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 you need to know before you are given ELAHERE

You must not receive ELAHERE

- if you are allergic to mirvetuximab soravtansine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Before you are given ELAHERE, talk to your doctor or nurse 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. ELAHERE could harm an unborn baby if taken during pregnancy.

Seek urgent medical attention if you have any of the following serious side effects (see section 4) during treatment:

- **Eye problems.** ELAHERE can cause severe eye problems such as loss of vision, damage to the cornea (the transparent layer in the front of the eye; keratopathy), dry eyes, abnormal sensitivity of the eyes to light (photophobia) or eye pain. You will see an eye specialist before starting treatment. It is important that you report any new or worsening eye problems before the start of each treatment cycle. It is recommended that you use drops to moisturise the eyes during treatment. If you develop certain side effects affecting the eyes, your doctor may recommend additional eye drops containing corticosteroids. You should not use contact lenses during treatment with ELAHERE unless advised by a healthcare professional. See 'Eye care' in section 3 for further information.
- **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 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 (paraesthesia), burning, pain, muscle weakness and distorted sense of touch (dysesthesia) in your arms or legs.
- **Infusion-related reactions.** Infusion-related reactions have occurred with ELAHERE. To minimise the risk of these reactions, your doctor will give you some medicines, see 'Medicines given before infusion' in section 3. In case of severe reactions, your doctor will stop the infusion immediately and you will be given supportive treatment.

If you experience any of the above-listed serious side effects, your doctor may withhold/reduce treatment until symptoms resolve, or in more serious cases, treatment will be permanently stopped.

Children and adolescents

This medicine must not be given to children or adolescents under 18 years because it has not been studied in this group.

Other medicines and ELAHERE

Tell your doctor if you are taking, have recently taken or might take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. This is because some medicines may affect the way ELAHERE works. Also, ELAHERE may affect the way other medicines work.

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)
- nefazodone (antidepressant)
- telithromycin (antibiotic for treating community acquired pneumonia)

Contraception

Women who could become pregnant must use an effective birth control (contraception) during treatment and for 7 months after the last dose of ELAHERE.

Pregnancy

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. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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.

Breast-feeding

Do not breast-feed during treatment and for 1 month after the last dose. ELAHERE may pass into breast milk.

Fertility

Fertility studies have not been conducted with ELAHERE and there are no data on the effect of the medicine on fertility. However, due to how the medicine works, 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, nerve damage causing pain, numbness or weakness in your hands, arms or feet, fatigue, or dizziness, do not drive, use tools, or operate machines until your symptoms are completely better.

ELAHERE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially 'sodium-free'.

ELAHERE contains polysorbate

This medicine contains 2.11 mg of polysorbate 20 in each vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How you will be given ELAHERE

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.

Medicines given before infusion

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

- Corticosteroids (such as dexamethasone) to help prevent inflammation
- Antihistamines (such as diphenhydramine) to help prevent allergic reactions
- Antipyretics (such as paracetamol) to reduce fever

You may 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.

Eye care

An eye care specialist will examine your eyes prior to starting treatment with ELAHERE.

- Before each treatment cycle, it is important that you tell your treating physician 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.

Contact lenses

- Do not wear contact lenses during treatment with ELAHERE, unless you are told to do so by your doctor or eye care specialist.

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.

Changes to your dose if you suffer from side effects

Your doctor will adjust your dose of ELAHERE if you suffer from any side effects (see section 4, Possible side effects).

If you are given more ELAHERE than you should have been given

Since the infusion is given to you by your doctor or specialist nurse, an overdose is unlikely. If you inadvertently receive too much medicine, your doctor will take appropriate measures to monitor and support you.

If a dose of ELAHERE is missed

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 stop treatment with ELAHERE

You should not stop treatment without talking with your doctor first.

The therapy with ELAHERE usually requires a number of treatment cycles. The number of infusions that you receive will depend on how your cancer is responding to treatment. Therefore, you should continue receiving ELAHERE even if you see your symptoms improve and until your doctor decides that ELAHERE should be stopped.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine.

Tell your doctor or nurse immediately or seek urgent medical attention if you experience any of the following side effects during or after treatment:

- **Eye problems** (very common – may affect more than 1 in 10 people): Signs or symptoms may include 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.
- **Inflammation in the lungs** (very common – may affect more than 1 in 10 people): Signs or symptoms may include 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.
- **Nerve damage in the arms and legs** (very common – may affect more than 1 in 10 people): 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 / hypersensitivity** (common – may affect up to 1 in 10 people): Signs and symptoms of infusion-related reactions may include 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.

Other side effects

Tell your doctor or nurse if you notice any of the following side effects:

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

- urinary tract infection – UTI (infection of the parts of the body that collect and pass out urine)
- low red blood cell counts which can cause tiredness and pale skin (anaemia)
- low blood platelet counts which can lead to bleeding and bruising (thrombocytopenia)
- loss of appetite
- low blood magnesium levels, symptoms include nausea, weakness, twitching, cramping or irregular heart beat (hypomagnesaemia)
- headache
- swollen belly (abdominal distension)
- belly (abdominal) pain
- diarrhoea
- constipation
- feeling sick (nausea)
- vomiting
- joint pain (arthralgia)
- tiredness
- blood tests showing an increase in aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels in blood, indicating liver problems

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

- low levels of neutrophils, a type of white blood cell that fights infection (neutropenia)
- low blood potassium levels which can cause weakness, muscle cramps, tingling, and heart rhythm disturbance (hypokalaemia)
- dehydration
- difficulty falling and staying asleep, and poor quality of sleep (insomnia)
- taste disturbance (dysgeusia)
- feeling dizzy

- high blood pressure (hypertension)
- build-up of fluid in the abdomen (ascites)
- disease where stomach acid rises up into the food pipe (gastro-oesophageal reflux disease)
- inflammation of the lining of the mouth (stomatitis)
- indigestion (dyspepsia)
- high blood bilirubin levels (hyperbilirubinemia) which may cause yellowing of skin or eyes
- itching (pruritis)
- muscle pain (myalgia)
- back pain
- pain in arms, hands, legs and feet
- muscle spasms
- blood tests showing an increase in alkaline phosphatase (ALP) levels and gamma-glutamyl transferase (GGT) levels in the blood, indicating liver problems
- weight loss

5. How to store ELAHERE

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

The following information is intended for healthcare professionals

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial label after EXP. The expiry date refers to the last day of that month.

Store the vials upright in a refrigerator (2 °C - 8 °C). Do not freeze. Do not shake.

Keep the vial in the outer carton in order to protect it from light.

If the diluted infusion solution is not used immediately, store it either at room temperature (15 °C - 25 °C) for no more than 8 hours (including infusion time), or in a fridge (2 °C - 8 °C) for no more than 24 hours followed by room temperature (15 °C - 25 °C) for no more than 8 hours (including infusion time).

Do not use this medicine if you notice the solution is cloudy or discoloured.

Do not throw away any medicines via wastewater. The hospital pharmacist will throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ELAHERE contains

- The active substance is mirvetuximab soravtansine, with 1 mL of concentrate for solution for infusion containing 5 mg of mirvetuximab soravtansine.
- The other ingredients are glacial acetic acid (E260), sodium acetate (E262), sucrose, polysorbate 20 (E432), and water for injections (see section 2).
- ELAHERE contains no preservatives and is intended for single dose only. Discard any unused solution remaining in the vial.

What ELAHERE looks like and contents of the pack

The medicine is a clear to slightly opalescent, colourless solution. It comes in a glass vial with a rubber stopper, an aluminium seal and royal blue flip cap.

Each pack contains 1 vial.

Product Registrant

AbbVie Pte. Ltd.

9 North Buona Vista Drive

The Metropolis #19-01

Singapore 138588

Date of issue: 21 Nov 2025