

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 receiving AMTAGVI?

AMTAGVI consists of your own white blood cells.

AMTAGVI is used to treat patients with cancer of the skin called melanoma. It is given when the cancer cannot be surgically removed or has spread to distant sites and other cancer medications have not worked.

AMTAGVI is given to adults aged 18 years and older.

For more information, see Section [1. Why am I receiving AMTAGVI?](#) in the full CMI.

2. What should I know before I receive AMTAGVI?

Do not use if you are allergic to AMTAGVI, cyclophosphamide, mesna, fludarabine, IL-2 (aldesleukin), 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 receive AMTAGVI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AMTAGVI 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 will I be given AMTAGVI?

- Your doctor will give you AMTAGVI at an authorised treatment centre. You will receive one treatment.

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

5. What should I know while receiving AMTAGVI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been given AMTAGVI. • Tell your doctor if you have any recent or active infections. • Use reliable contraception before, during, and after treatment. For more information, see Section 2. What should I know before I receive AMTAGVI? in the full CMI.
Things you should not do	• Do not have certain vaccines called live vaccines.
Driving or using machines	• Do not drive or operate heavy or potentially dangerous machines for at least 3 weeks after infusion due to the potential of side effects that may impact your ability to drive and use machines.
Looking after your medicine	• Your doctor will treat you with AMTAGVI. There is no need to store this medicine at home.

For more information, see Section [5. What should I know while receiving AMTAGVI?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, the AMTAGVI regimen can cause side effects, although not everybody gets them. Some side effects may be serious or life-threatening. Get medical help straight away if you get any of the following serious side effects which may be severe and can be fatal:

- A serious condition called 'capillary leak syndrome' or a serious condition called 'cytokine release syndrome'
- Sudden onset chest pain and shortness of breath and irregular or fast heartbeat that does not return to normal with rest
- Signs of infections, some of which may be life threatening

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.

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, INTERNAL ORGAN HAEMORRHAGE, CARDIOPULMONARY and RENAL IMPAIRMENT

Severe and fatal adverse reactions have occurred in patients treated with the AMTAGVI regimen, including:

- Prolonged severe cytopenia and severe infections.
- Internal organ hemorrhage
- Cardiopulmonary impairment
- Renal impairment

AMTAGVI is administered as a one-time treatment in an authorised treatment centre under the supervision of a physician experienced in the use of anti-cancer agents.

AMTAGVI® (am-tag-vee)

Active ingredient(s): *lifileucel* (life-ah-lew-cell)

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMTAGVI. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AMTAGVI.

Where to find information in this leaflet:

- [1. Why am I receiving AMTAGVI?](#)
- [2. What should I know before I receive AMTAGVI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given AMTAGVI?](#)
- [5. What should I know while receiving AMTAGVI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving AMTAGVI?

AMTAGVI contains the active ingredient lifileucel.

AMTAGVI is an autologous (made from your own cells) T-cell immunotherapy.

Your healthcare team may consider AMTAGVI if you are an adult with a type of skin cancer that cannot be removed surgically or has spread to other parts of the body called unresectable or metastatic melanoma. AMTAGVI is used when:

- your melanoma has not responded or stopped responding to a cancer medicine called a PD-1 blocker either by itself or in a combination, and
- if your cancer has a mutation (change) in the BRAF gene and you have previously been treated with a

cancer medicine that blocks the BRAF protein, either by itself or in combination.

2. What should I know before I receive AMTAGVI?

Warnings

Do not use AMTAGVI if:

- you are allergic to lifileucel, cyclophosphamide, fludarabine, mesna, IL-2 (aldesleukin), 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 any other medical conditions including, lung, heart, liver or kidney problems, or low blood pressure.
- have a recent or active infection including cytomegalovirus (CMV) infection, hepatitis B or C or human immunodeficiency virus (HIV).
- have a recent or active inflammatory condition.
- notice the symptoms of your cancer are getting worse.
- have been taking a blood thinner.
- take any medicines for any other condition.

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

AMTAGVI should only be given if you are not pregnant.

Use reliable contraception during treatment and for 12 months after treatment. If you are a male patient and have a partner who can become pregnant, use reliable contraception during and for 6 months after treatment.

You should not breastfeed during treatment with AMTAGVI. This is because the effects of AMTAGVI in pregnant or breastfeeding women are not known.

Children and adolescents

This medicine should not be used in children and adolescents below 18 years of age as the medicine has not been studied in this age group and it is not known if it is safe and effective.

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.

Medicines that affect your immune system

Before you are given AMTAGVI or IL-2 (aldesleukin), tell your doctor or nurse if you are taking any medicines that weaken your immune system such as:

- Medicines called glucocorticoids (a type of steroid), used to treat inflammatory reactions.

This is because these medicines may interfere with the effect of AMTAGVI or IL-2 (aldesleukin).

Vaccines and AMTAGVI

You must not be given certain vaccines called live vaccines:

- in the 28 days before you are given lymphodepleting chemotherapy including the two drugs cyclophosphamide and fludarabine to prepare your body to receive the AMTAGVI.
- during treatment.
- 3 months after treatment while the immune system is recovering.

Talk to your doctor if you need to have any vaccinations.

Medicines that may interact with IL-2 (aldesleukin)

Before you are given AMTAGVI, tell your doctor or nurse if you are taking any medicines that may interact with IL-2 (aldesleukin) (a medicine you will be given after you receive AMTAGVI). These include the following:

- Chemotherapy medicines, called tamoxifen, interferon-alpha, cisplatin, vinblastine and/or dacarbazine, used to treat cancer.
- Medicines called beta-blockers, used to treat high blood pressure.
- Medicines that affect the heart, central nervous system, liver, kidneys, or bone marrow.

- Contrast fluids used in computerised tomography (CT) scanning.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AMTAGVI.

4. How will I be given AMTAGVI?

AMTAGVI will always be given to you by a healthcare professional at an authorised treatment centre.

Making AMTAGVI from your tumour tissue

A small piece of your tumour tissue will be removed, possibly during an outpatient procedure. This tissue is used to collect your own white blood cells to make your individualised AMTAGVI therapy.

- The location of your tumour tissue in your body determines which specialised surgeon will perform this procedure.
- If you have multiple tumours, your treatment centre team in partnership with specialised surgeons will determine the best location to collect your tumour tissue from.
- If your procedure is outpatient, some patients may return home the same day of the procedure.
- After your tumour tissue is removed, it is then shipped to a specialised manufacturing facility to create your AMTAGVI therapy.

Medicines you will receive before AMTAGVI treatment

After your AMTAGVI arrives at your authorised treatment centre, your healthcare provider will give you lymphodepleting chemotherapy including the two drugs cyclophosphamide and fludarabine over 7 days to prepare your body.

Approximately 30 to 60 minutes before you receive AMTAGVI, you will receive other medicines including:

- Medicines that help to prevent an allergic reaction (anti-histamines).
- Medicines for fever (such as paracetamol).

How AMTAGVI is given

When your body is ready, your healthcare provider will give AMTAGVI to you by intravenous infusion. Your AMTAGVI will be provided in 1 to 4 patient-specific infusion bag(s) containing approximately 100 mL of viable (alive) cells per bag.

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

After AMTAGVI is given

Beginning 3 to 24 hours after this medicine is given, you will be given up to 6 doses of IL-2 (aldesleukin) every 8 to 12 hours via intravenous infusion. This treatment is given to support AMTAGVI activity within your body. Your doctor will stop IL-2 (aldesleukin) infusion any time if you have severe side effects.

You will have to stay in the treatment centre until you have completed the IL-2 (aldesleukin) treatment and you have recovered from any possible serious side effects you might have that are associated with the AMTAGVI treatment.

5. What should I know while receiving AMTAGVI?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you have been given AMTAGVI.

Driving or using machines

Do not drive or use any machines or tools for at least 3 weeks after infusion.

The AMTAGVI treatment regimen has a major influence on the ability to drive and use machines. Dizziness (common), tiredness (very common), or weakness (very common) are possible side effects.

Wait until these effects have worn off before you drive or use machines.

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 or lead to death.

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

Less serious side effects

Less serious side effects	What to do
Side effects affecting the metabolic system: changes in appetite or weight; increased fluid in the body; dehydration; increased acid in the blood	Speak to your doctor if you have any of these less serious side effects and they worry you.
Side effects affecting the nervous system: trouble sleeping; excessive worrying; confused thinking and reduced awareness of surroundings; feeling sad; headache; altered mental state; dizziness; nerve damage that may cause numbness, pain, and weakness; foul, salty, rancid, or metallic taste sensation in the mouth; and difficulty speaking or understanding	
Changes in sight or hearing:	

difficulty seeing; double vision; difficulty hearing; ringing in the ears; loss of hearing	
Side effects affecting the circulatory system: high or low blood pressure; bleeding; reddening of the face; swelling of your arm or leg, which may indicate blood clots or blockages in your blood vessels	
Side effects affecting the nose, throat or lungs: difficulty breathing; cough; low blood oxygen that can cause shortness of breath, a fast heartbeat, confusion, headache or tiredness; fluid around the lungs that can cause shortness of breath, crackles in the lungs; throat pain; stuffy nose	
Side effects affecting the gut: nausea; diarrhoea; vomiting; stomach pain; dry mouth; soreness or inflammation in the mouth; bloating, swelling, or discomfort in the belly; inflammation of the gut that can cause cramping, diarrhoea, and blood in the stool	
Skin-related: rash; itching; a condition called 'vitiligo' with patches of skin turning lighter than the surrounding skin; skin redness; dry skin; excessive sweating	
Hair loss	
Muscle- or joint-related muscle and joint pain; muscle weakness; muscle cramping	

Serious side effects

Serious side effects	What to do
A serious condition called 'capillary leak syndrome'; some signs include: - low blood pressure, which can make you feel dizzy or lightheaded - fever and chills - fast heartbeat - swelling of the feet, ankles, legs, and arms	Seek immediate medical attention should signs and symptoms of capillary leak syndrome occur.

• puffiness around the eyes • feeling very tired or weak	
An immune condition called ‘cytokine release syndrome’; some signs include: • fever (38°C or higher, which can also be a sign of infection), which may be accompanied by: • chills • fast heartbeat • difficulty breathing • low blood pressure, which can make you feel dizzy or lightheaded	Seek immediate medical attention should signs and symptoms of cytokine release syndrome occur.
Heart-related: • sudden onset chest pain and shortness of breath which could indicate a heart attack; irregular heartbeat; fast heartbeat not returning to normal with rest	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.
A potentially serious condition that can affect the eyes called ‘uveitis’; some signs include: • eye redness and pain • light sensitivity • blurred vision • dark floating spots in the field of vision	
Lung-related: Blood clots in the lungs that may make it harder for your lungs to get oxygen into your body. Some signs include: • shortness of breath • chest pain • coughing • feeling lightheaded A serious condition called ‘acute respiratory failure’ where the lungs cannot work well enough to support normal breathing. Symptoms can include: • Severe shortness of breath • Fast or difficult breathing • Feeling unable to get enough air • Bluish lips or skin due to low oxygen • Confusion, drowsiness, or unusual sleepiness • Extreme tiredness	
Kidney-related: • The kidneys may suddenly stop working, which may cause	

decreased urine output, swelling in your legs or other parts of your body, nausea, confusion, or shortness of breath. • Kidney damage; frequent urination; discomfort, pain, or burning when urinating; loss of bladder control; difficulty urinating; a sudden urge to urinate; decreased urination	
An increased risk of life-threatening infections, symptoms of which can include: • fever; chills; cough; shortness of breath; rapid breathing; rapid pulse	
Haemorrhage, including internal organ haemorrhage: • Bleeding from any part of the body, including the inside of the body. Signs of bleeding on the inside of the body may include dizziness, tiredness, difficulty breathing, or pain in one area of the body.	
A disease of the brain called ‘encephalopathy’; symptoms can include: • Altered thinking, disturbance in mental abilities, confused thinking and reduced awareness of the surroundings	
A serious condition called ‘immune effector-cell associated neurotoxicity’; symptoms can vary from mild to severe and may include: • Confusion or trouble thinking clearly • Difficulty speaking or finding words • Sleepiness or reduced alertness • Headache • Shaking (tremor) • Seizures	

You may experience the following side effects when your doctor orders blood tests:

- low number of white blood cells (neutrophils, leukocytes, lymphocytes)
- low numbers of red blood cells (anaemia)
- low numbers of platelets (help blood to clot)
- low levels of calcium, potassium, magnesium, sodium, phosphorus in the blood
- low levels of albumin and protein in the blood
- high or low blood sugar

- increased levels of enzymes in the blood (alkaline phosphatase, creatine phosphokinase, gamma-glutamyltransferase, transaminases)
- high level of bilirubin in the blood
- increased level of C-reactive protein in blood (may indicate infection or inflammation)

Tell your doctor 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. 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.

One individual dose includes 1 to 4 infusion bags with approximately 100 mL of cell dispersion per bag. (ARTG 527457).

Who distributes AMTAGVI?

IOVANCE AUSTRALIA PTY LTD

c/o McBurneys Chartered Accountants & Business Advisors

Level 10, 68 Pitt Street

Sydney, NSW 2000

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This leaflet was prepared in June 2026.

7. Product details

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

What AMTAGVI contains

Active ingredient (main ingredient)	lifileucel
Other ingredients (inactive ingredients)	• CryoStor CS10 (contains dimethyl sulfoxide (DMSO)) • Multiple Electrolytes Injection, Type 1, USP (Plasma-Lyte A) • Human serum albumin (HSA) • Interleukin-2 • Water for injections
Potential allergens	• gentamicin • streptomycin

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

What AMTAGVI looks like

This medicine is a colourless to dark yellow dispersion for infusion.

Each infusion bag is stored and shipped within one protective aluminium cassette.

AMTAGVI is shipped from the manufacturing facility to the treatment centre storage facility in a specialised container that may contain multiple metal cassettes intended for a single patient.