

Alburex[®] 5 AU

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.

1. Why am I being given Alburex[®] 5 AU?

Your healthcare provider has decided Alburex[®] 5 AU is appropriate for you. Alburex[®] 5 AU contains the active ingredient human albumin. Alburex[®] 5 AU is used to restore and maintain circulating blood volume where volume deficiency has been demonstrated.

For more information, see Section [1. Why am I being given Alburex[®] 5 AU?](#) in the full CMI.

2. What should I know before I am given Alburex[®] 5 AU?

Do not use if you have ever had an allergic reaction to Alburex[®] 5 AU 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 or are on a sodium controlled diet.

For more information, see Section [2. What should I know before I am given Alburex[®] 5 AU?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Alburex[®] 5 AU and affect how it works.

For more information see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Alburex[®] 5 AU?

- Your doctor will be responsible for determining the amount and infusion rate of Alburex[®] 5 AU that you are to receive, as appropriate for your condition.
- Follow the instructions provided by your doctor.

More instructions can be found in Section [4. How will I be given Alburex[®] 5 AU?](#) in the full CMI.

5. What should I know after I am given Alburex[®] 5 AU?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Alburex[®] 5 AU.• Notice any signs of a serious side effect – this may indicate that the administration of Alburex[®] 5 AU should be stopped.
Driving or using machines	<ul style="list-style-type: none">• Alburex[®] 5 AU does not affect your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Do not freeze. Protect from light.• Do not use after the expiry date.

For more information, see Section [5. What should I know after I am given Alburex[®] 5 AU?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

Alburex[®] 5 AU

Active ingredient: *human albumin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Alburex[®] 5 AU. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about using Alburex[®] 5 AU.**

Where to find information in this leaflet:

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

1. Why am I being given Alburex[®] 5 AU?

Your healthcare provider has decided Alburex[®] 5 AU is appropriate for you.

Alburex[®] 5 AU contains human albumin as the active ingredient.

Alburex[®] 5 AU is made from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood.

Alburex[®] 5 AU solution for intravenous infusion is used under medical supervision to restore and maintain blood volume in situations when your blood volume has or is at risk of critical decrease.

This may be the case, for example:

- due to severe loss of blood after an injury *or*
- due to a large surface burn.

The choice of using Alburex[®] 5 AU will be made by your doctor. It will depend on your individual clinical situation.

Alburex[®] 5 AU stabilises the circulating blood volume. It is a carrier of hormones, enzymes, medicines and toxins. The albumin protein in Alburex[®] 5 AU is isolated from human blood plasma. Therefore the albumin works exactly as if it was your own protein.

2. What should I know before I am given Alburex[®] 5 AU?

Warnings

You must not be given Alburex[®] 5 AU if:

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

Check with your doctor if you currently have or had in the past, at least one of these conditions:

- are on a sodium controlled diet
- allergies to any food or medicine
- heart insufficiency which needs to be treated with medicines (decompensated cardiac insufficiency)
- high blood pressure (hypertension)
- expansion of the gullet vein (oesophageal varices)
- abnormal accumulation of liquid in the lung (pulmonary oedema)
- predisposition for bleeding (haemorrhagic diathesis)
- severe decrease of red blood cells (severe anaemia)
- severe decrease of urine excretion because of kidney disease or outflow impairment (renal and post-renal anuria).

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?](#)

Pregnancy and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will decide whether you can receive Alburex[®] 5 AU during your pregnancy or while you are breastfeeding.

Virus safety

Alburex[®] 5 AU is made from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood. When medicines are made from human blood and injected into you, it is possible that viruses or other substances could be present in the medicine and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or parvovirus B19 and theoretically Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents, some of which may not yet have been discovered.

To reduce the risk of this happening, extra steps are taken when manufacturing this medicine. Strict controls are

applied when selecting blood donors and donations. The medicine is specially treated to remove or kill certain viruses. This special treatment is considered effective against certain viruses known as enveloped viruses such as HIV, hepatitis B and hepatitis C viruses, and the non-enveloped viruses, hepatitis A and parvovirus B19.

Despite these measures, the risk of viral and other agents' infectivity cannot be totally eliminated.

Alburex® 5 AU contains sodium

Alburex® 5 AU contains approximately 3.2 mg sodium per 1 mL. Please take this into account if you are on a sodium controlled diet.

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.

No specific interactions of Alburex® 5 AU with other medicines are known.

However tell your doctor before treatment if you are taking, have recently taken or might take any other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Alburex® 5 AU.

4. How will I be given Alburex® 5 AU?

How much will I be given

Your doctor will be responsible for determining the amount and infusion rate of Alburex® 5 AU that you are to receive, as appropriate for your condition.

Your doctor will give you Alburex® 5 AU as an infusion, that is, an injection given slowly into the vein.

Your doctor will regularly monitor important blood flow values like:

- your blood pressure
- your pulse rate
- your urine output
- your blood tests.

These values are monitored to determine the right dose and infusion rate.

When will Alburex® 5 AU be given

Alburex® 5 AU should be used to restore and stabilise the circulating blood volume. It is normally used under intensive care situations, when your blood volume has decreased critically.

If too much Alburex® 5 AU is given

Alburex® 5 AU is administered under medical supervision only. An overdose is therefore very unlikely to occur. An abnormal increase in blood volume (hypervolaemia) may

occur if the dosage and infusion rate are too high. This may lead to an overload of the heart and circulatory system (cardiovascular overload).

Tell your doctor if you notice the following symptoms of an overdose:

- headache
- breathing difficulty
- swelling of your neck veins (jugular vein congestion).

Your doctor may also detect signs like:

- an increased blood pressure
- a raised central venous pressure
- an abnormal accumulation of liquid in the lung (pulmonary oedema).

In all these cases, your doctor will stop the infusion and monitor your circulation as necessary.

5. What should I know after I am given Alburex® 5 AU?

Things you should do

Call your doctor straight away if you:

- notice signs of an allergic reaction (hypersensitivity reaction). These may occur and may very rarely be severe enough to cause shock (see **Side effects**) Your doctor will decide to stop the infusion completely and start the appropriate treatment.
- notice signs of an abnormal increase in blood volume (hypervolaemia). This may occur if the dosage and infusion rate are not adjusted to your condition. This may lead to an overload of the heart and circulatory system (cardiovascular overload). First signs of such an overload are headache, breathing difficulty or swelling of your neck (jugular vein congestion). Your doctor will stop the infusion and monitor your circulation as necessary.

Remind any doctor or dentist you visit that you are using Alburex® 5 AU.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Alburex® 5 AU affects you.

Alburex® 5 AU does not affect your ability to drive and use machines.

Looking after your medicine

- Store below 30°C.
- Do not freeze.
- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date
- Keep the vial in the outer carton in order to protect from light.
- Do not use this medicine if you notice that the solution is cloudy or has particles.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• flushing• itchy rash (urticaria)• fever• nausea. <p>They will normally disappear rapidly when the infusion is slowed down or the infusion is stopped.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Symptoms of an allergic reaction may include any, some or many of the following:</p> <ul style="list-style-type: none">• feeling faint (fall in blood pressure)• dizziness• irregular or faster heart beat• skin reactions, e.g. redness, itching, swelling, blistering, rash or hives (itchy bumps)• difficulty breathing, e.g. wheezing, chest tightness, shortness of breath or cough• swelling of the face, eyelids, lips, tongue or throat• cold-like symptoms, e.g. stuffy or runny nose, sneezing, red, itchy, swollen or watery eyes• headache, stomach ache, nausea, vomiting or diarrhoea.	<p>Tell your doctor immediately if you notice any of these serious symptoms which may be signs of serious allergy, as the infusion of Alburex® 5 AU should be stopped.</p>

Tell your doctor 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.

7. Product details

Alburex® 5 AU is usually given in a hospital.

What Alburex® 5 AU contains

Active ingredient (main ingredient)	Human albumin
Other ingredients (inactive ingredients)	sodium acetyltryptophanate sodium octanoate sodium chloride

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

What Alburex® 5 AU looks like

Alburex® 5 AU is a solution for infusion. It is a clear, slightly viscous liquid. It is almost colourless, yellow, amber or green.

Alburex® 5 AU is issued in glass vials in two sizes:

The 250 mL vial contains 12.5 g of human albumin.

The 500 mL vial contains 25 g of human albumin.

250 mL AUST R 327950

500 mL AUST R 327951

Who distributes Alburex® 5 AU

Manufacturer

Alburex® 5 AU is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189–209 Camp Road

Broadmeadows VIC 3047

Distributor

Australian Red Cross Lifeblood

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