Alburex® 20 NZ

Human albumin

Solution for intravenous infusion.

What is in this leaflet

This leaflet answers some common questions about Alburex® 20 NZ. It does not contain all the available information about Alburex® 20 NZ. It does **not** take the place of talking to your doctor.

All medicines have benefits and risks. Your doctor has weighed the benefits that Alburex® 20 NZ will have for you against the risks.

If you have any concerns about using this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference. The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated with this medicine.

What Alburex® 20 NZ is used for

Alburex® 20 NZ is used to restore and stabilise the circulating blood volume. It is normally used under intensive care situations, when your blood volume has decreased critically. 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® 20 NZ will be made by your doctor. It will depend on your individual clinical situation.

Ask your doctor if you have any questions about why Alburex® 20 NZ has been prescribed for you.

How Alburex® 20 NZ works

Albumin stabilises the circulating blood volume. It is a carrier of hormones, enzymes, medicines and toxins. The albumin protein in Alburex® 20 NZ is isolated from human blood plasma. Therefore the albumin works exactly as if it was your own protein.

Before you are given Alburex® 20 NZ

When you must not receive it

Do not receive Alburex® 20 NZ if you are allergic to:

- human albumin
- any of the ingredients listed at the end of this leaflet.

Before you are given it

Tell your doctor before treatment if you currently have or had in the past, at least one of these conditions:

- 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).

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. Your doctor will decide whether you can receive Alburex® 20 NZ during your pregnancy or while you are breast-feeding.

Tell your doctor if you are on a sodium controlled diet. This medicine contains sodium which should be taken into consideration.

Taking other medicines

No specific interactions of Alburex® 20 NZ with other medicines are known.

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

About blood products

Alburex® 20 NZ is manufactured from human plasma (the liquid component of blood) collected by the New Zealand Blood Service. 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 viruses known as enveloped viruses such as HIV, and hepatitis B and C viruses, and the non-enveloped virus, hepatitis A and parvovirus B19. Despite the measures taken, the risk of viral and other agents' infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this medicine with your doctor.

How Alburex® 20 NZ is given

Your doctor will be responsible for determining the amount and infusion rate of Alburex® 20 NZ that you are to receive, as appropriate for your condition. Your doctor will give you Alburex® 20 NZ 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 stopping the infusion may be required?

Allergic reactions (hypersensitivity reactions) may occur and may very rarely be

severe enough to cause shock (see **Side effects**).

Tell your doctor immediately if you notice such reactions during the infusion. Your doctor will decide to stop the infusion completely and start the appropriate treatment.

An abnormal increase in blood volume (hypervolaemia) may occur if the dosage and infusion rate are not adequately 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 veins (jugular vein congestion).

Tell your doctor immediately if you notice such signs. Your doctor will stop the infusion and monitor your circulation as necessary.

An abnormal increase in body water content (hyperhydration) may occur if you are not appropriately hydrated for the dosage and infusion rate given. Your doctor will monitor this closely. First signs of body water overload are headache, confusion, irritability and drowsiness.

Tell your doctor immediately if you notice such signs. Your doctor will stop the infusion and monitor your fluid status as necessary.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Such side effects may occur even when you have previously received Alburex® 20 NZ and had tolerated it well.

Tell your doctor as soon as possible if you do not feel well while you are being given Alburex® 20 NZ.

Severe allergic reactions (hypersensitivity reactions) may occur very rarely. Tell your doctor immediately if you notice any of the following symptoms which may be signs of serious allergy or anaphylaxis, as the infusion of Alburex® 20 NZ should be stopped:

- 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, stomachache, nausea, vomiting or diarrhoea.

Tell your doctor if you notice any of the following and they worry you:

- flushing
- itchy rash (urticarial)
- fever
- nausea.

They will normally disappear rapidly when the infusion is slowed down or the infusion is stopped.

Talk to your doctor if you get any side effects. This includes any possible side effects not listed in this leaflet.

Do not be alarmed by this list of possible side effects.

Overdose

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.

How to store Alburex® 20 NZ

Store below 25°C. Do not freeze. Protect from light. Do not use after the expiry date. Keep out of reach of children.

Further information

Alburex® 20 NZ can only be obtained on a doctor's prescription. This leaflet does not contain all the available information about Alburex® 20 NZ. If you need more information about Alburex® 20 NZ and your treatment in general, or if you have any questions or are not sure about something in this leaflet, ask your doctor.

Product description

What it looks like

Alburex® 20 NZ is a clear and slightly viscous liquid. It is almost colourless, yellow, amber or green.

Ingredients

The 50 mL vial contains 10 g of human albumin.

The 100 mL vial contains 20 g of human albumin.

Alburex® 20 NZ also contains sodium acetyltryptophanate, sodium octanoate and sodium chloride.

Sponsor details

Alburex® 20 NZ is supplied in New Zealand by:

CSL Behring (NZ) Limited

PO Box 62590
Greenlane
Auckland 1546
NEW ZEALAND

0800 640 677

Distributor

New Zealand Blood Service

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