

Albumex® 20

Human albumin, solution for intravenous infusion.

Consumer Medicine Information

What is in this leaflet

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

All medicines have benefits and risks. Your doctor has weighed the benefits that Albumex® 20 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.

What Albumex® 20 is used for

Albumex® 20 may be used:

- in an acutely ill patient when the amount of protein in their blood is low (hypoproteinaemia)
- to replace fluid in the blood vessels due to acute loss of blood or plasma (plasma is the non-cellular part of the blood)
- to treat extensive burns
- to treat a serious lung condition (respiratory distress syndrome)
- in procedures where the patient's blood is purified (haemodialysis)

- in procedures where the patient's plasma is replaced (plasma exchange).

The main functions of Albumex® 20 are to replace and retain fluid in the blood vessels and to carry other chemicals through the blood stream.

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

Before you are given Albumex® 20

When you must not take it

Do not take Albumex® 20 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 if you:

- are allergic to any other food or medicine
- have any other medical conditions such as a history of heart or kidney disease, low blood pressure, breathing difficulties, decreased number of red blood cells (anaemia) or a tendency to bleed or bruise easily
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.
- are pregnant or breastfeeding
- are on a controlled or low sodium diet.

If you want further information, consult your doctor.

About blood products

Albumex® 20 is manufactured from human plasma (the liquid component of blood) collected by the Australian Red Cross 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 the 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 and 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. This treatment also reduces the risk of parvovirus B19 exposure. Despite these measures, the risk of viral and other agent's 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.

How to use Albumex® 20

Your doctor will be responsible for determining the dose(s) of Albumex® 20 that you are to receive, as appropriate for your condition. Your doctor will give you Albumex® 20 as an infusion, that is, an injection given slowly into the vein.

Side effects

Along with their intended effects, medicines may cause some unwanted side effects, which can sometimes be serious. Furthermore, individual patients may react differently to similar doses of the same medicine. This applies to Albumex® 20, although severe reactions during/after Albumex® 20 administration are rare. You may need medical treatment if you get some of the side effects.

Tell your doctor immediately if you notice any of the following symptoms which may be signs of a serious allergy or anaphylaxis, as the infusion of Albumex® 20 should be stopped:

- feeling faint (fall in blood pressure)
- irregular or faster heart beat
- difficulty in breathing
- reddening of the skin (flushing)
- dizziness
- rash
- feeling sick.

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

- nausea or vomiting
- chills or fever
- itching
- muscle spasms
- high blood pressure.

Some laboratory abnormalities have also been associated with albumin administration. Your doctor may take blood samples to closely

monitor some important elements in your body.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects during or after treatment with Albumex® 20.

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

This medicine does not generally cause any undesired reactions.

Overdose

Administering a larger than recommended dose to patients with heart failure, certain kidney diseases and long-standing anaemia (decreased number of blood cells), or to patients on heart-lung bypass, may have harmful side effects. During treatment with Albumex® 20, such patients will be observed closely.

Storing Albumex® 20

10 mL bottle: Store at 2°C to 8°C (Refrigerate. Do not freeze).

100 mL bottle: Store below 30°C (Do not freeze).

Protect from light. Do not use after the expiry date.

Further information

Albumex® 20 can only be obtained on a doctor's prescription. This leaflet does not contain all the available information about Albumex® 20. If you need more information about Albumex® 20 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

Albumex® 20 is a clear or slightly non-transparent, almost colourless, yellow, amber or green solution. It is available in glass bottles of 10 mL and 100 mL.

Ingredients

Each bottle of Albumex® 20 is a sterile solution containing human albumin.

- The 10 mL bottle contains 2 g of human albumin;
- the 100 mL bottle contains 20 g of human albumin.

Albumex® 20 also contains sodium octanoate.

Manufacturer

Albumex® 20 is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Distributor

Australian Red Cross Blood Service

Date of most recent amendment

September 2016

Australian Register Numbers

10 mL: AUST R 31820

100 mL: AUST R 46283

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