National Office
Private Bag 92071
Victoria Street West
Auckland 1142
New Zealand
Telephone: 64-9-523 5744

19th June 2024

Hospital Transfusion Committee Chairs
Blood Bank Team Leaders
PLEASE CIRCULATE AS REQUIRED

Dear Colleagues

Re: Plasma Product Changes 2024 - ALBUREX® 20 NZ is replacing ALBUMEX® 20

As part of the change in New Zealand's plasma product portfolio, both the 10mL and 100mL vials of ALBUMEX® 20 will be replaced by one preparation, **ALBUREX® 20 NZ, 100mL,** a human albumin 20% colloid solution, manufactured from New Zealand (NZ) plasma.

What to expect and timelines

ALBUREX® 20 NZ will be transitioned into NZ clinical settings in a staged manner and is dependent on the run-out of ALBUMEX® 20 inventory to ensure product is not wasted. The Transfusion Nurse Specialist team will provide site-specific details, closer to the transition-time. Key milestones, are as follows:

From 22 July 2024	**ALBUREX® 20 NZ, 100mL** will be available to order by all non-NZBS Blood Banks; and can be issued to patients once the local inventory of ALBUMEX® 20 is depleted.
During August 2024	The national ALBUMEX® 20 inventory will be utilised by the six NZBS Blood Banks (Auckland, Waikato, Palmerston North, Wellington, Christchurch, and Dunedin). Once all inventory is run out, **ALBUREX® 20 NZ, 100mL** will be introduced. Current modelling suggests this should be completed during August.
8 October 2025	Any remaining ALBUMEX® 20, 10mL will be retired (batch expiry).

ALBUREX® 20 NZ resources to support the change

- The Medsafe website provides both the ALBUREX® 20 NZ, 100mL datasheet and ALBUREX® 20 NZ, 100mL Consumer Medicines Information (CMI)

- The NZBS Transfusion Medicine Handbook 5.3.3 . now includes **ALBUREX® 20 NZ**
- Before the product is ready for release, your local Transfusion Nurse Specialist, CNS Transfusion or Blood Bank, will provide **ALBUREX® 20 NZ** information flyer's, outlining the key product differences; and a revised *'Your Guide to Blood Transfusion Leaflet - Human Albumin Blood Products'* to support informed consent.
- More information is available at CSL Behring Plasma Product Transition Hub

Thank you for your support in ensuring a safe and effective move to these transitioned products.

Please direct any queries to plasmaproductschange@nzblood.co.nz

Yours faithfully

DR GAVIN CHO
Acting Chief Medical Officer

cc: *NZBS Senior Team*
Transfusion Medicine Specialist Team
Transfusion Nurse Specialist Team
Esther Hamelink, Jomyn Diedericks, Graeme Sykes,
Registrars
Component Processing
Donation Accreditation
Cellular Therapies Laboratory

Att: *160S035 Data Sheet – Alburex 20 NZ*
111I096 Alburex 20 NZ CMI
111I160 Alburex 20 NZ Information Flyer

NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Alburex® 20 NZ, 20% (200 g/L), solution for infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Human albumin

Alburex® 20 NZ is a solution containing 200 g/L of total protein of which at least 96% is human albumin.

Alburex® 20 NZ is manufactured from human plasma donated by New Zealand's voluntary and non-remunerated donors.

Excipients with known effect:

One litre of Alburex® 20 NZ also contains 16 mmol of sodium acetyltryptophanate and 16 mmol of sodium octanoate. Sodium chloride is added to give a sodium content of 140 mmol/L.

For the full list of excipients, see section 6.1.

One litre of Alburex® 20 NZ contains a total of 32.4 g of nitrogen.

3 PHARMACEUTICAL FORM

Solution for infusion.

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

Alburex® 20 NZ is hyperoncotic to normal plasma. It has a nominal osmolality of 258 mOsm/kg, is isotonic and the pH is 6.7–7.3.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid is appropriate.

The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient.

4.2 Dose and method of administration

Dose

The concentration of the albumin preparation, dosage and the infusion rate should be adjusted to the patient's individual requirements.

The dose required depends on the size of the patient, the severity of trauma or illness and on continuing fluid and protein losses. Measures of adequacy of circulating volume and not plasma albumin levels should be used to determine the dose required. Infusion rate and volume need to be adapted according to clinical conditions, most notably in the elderly or in the paediatric population.

Monitoring advice

If Alburex® 20 NZ is to be administered, haemodynamic performance should be monitored regularly. This may include:

- arterial blood pressure and pulse rate
- central venous pressure
- pulmonary artery wedge pressure
- urine output
- electrolyte
- haematocrit/haemoglobin.

Paediatric population

The dosage in children and adolescents (0–18 years) should be adjusted to the patient's individual requirements.

Method of administration

Alburex® 20 NZ should be administered by the intravenous route only.

The product is ready for use and can be administered as supplied either directly or it can first be diluted to a mildly hypooncotic solution to normal plasma (4–5% albumin) prior to administration, in the proportion of 1 mL of Alburex® 20 NZ to 4 mL of suitable crystalloid solution.

Alburex® 20 NZ is packaged in a glass vial that must be vented during use.

The infusion rate should be adjusted according to the individual circumstances and the indication. In plasma exchange the infusion rate should be adjusted to the rate of removal.

For instructions on dilution of the medicine before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to albumin preparations or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the infusion. In case of shock, standard medical treatment for shock should be implemented.

Albumin should be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk for the patient. Examples of such conditions are:

- decompensated cardiac insufficiency

- hypertension
- oesophageal varices
- pulmonary oedema
- haemorrhagic diathesis
- severe anaemia
- renal and post-renal anuria.

The colloid-osmotic effect of human albumin 200 g/L is approximately four times that of blood plasma. Therefore, when concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration. Alburex® 20 NZ must not be diluted with water for injections as this may cause haemolysis in recipients.

200–250 g/L human albumin solutions are relatively low in electrolytes compared to the 40–50 g/L human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.

If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

Hypervolaemia may occur if the dosage and infusion rate are not adjusted to the patient's circulatory situation. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary oedema, the infusion is to be stopped immediately.

Alburex® 20 NZ contains approximately 3.2 mg sodium per mL of solution (140 mmol/L). This should be noted when the product is used in patients requiring sodium restriction.

Pathogen safety

This product is made from human plasma. Products made from human plasma may contain infectious agents such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain infectious agents and by testing for the presence of certain viral markers.

The Alburex® 20 NZ manufacturing process includes pasteurisation (60°C for 10 hours) and multiple steps involving ethanol fractionation and depth filtration in the presence of filter aids which contribute to the reduction of pathogens should they be present. The current process and procedures applied in the manufacture of this product are effective against enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and the non-enveloped virus, hepatitis A virus (HAV) and human parvovirus B19.

Despite these measures, such products may still potentially transmit disease. There is also the possibility that other known or unknown infectious agents may be present in such products.

Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate.

It is strongly recommended that every time that Alburex® 20 NZ is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

4.5 Interaction with other medicines and other forms of interaction

No specific interactions of human albumin with other medicinal products are known.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproductive toxicity studies with Alburex® 20 NZ in animals have not been conducted.

The use of Alburex® 20 NZ in human pregnancy has not been established in controlled clinical trials; therefore, use in pregnant women only if benefits outweigh risk.

Breast-feeding

Like endogenous serum albumin, Alburex® 20 NZ may be excreted in milk. No safety information is available.

Fertility

No studies examining the effect of Alburex® 20 NZ on fertility have been conducted.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and use machines have been observed.

4.8 Undesirable effects

Summary of the safety profile

Mild reactions with human albumin solutions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe allergic reactions such as anaphylactic shock may occur. In these cases, the infusion should be stopped immediately and an appropriate treatment should be initiated.

Tabulated list of adverse reactions

Table 1 presents the adverse reactions which have been observed with CSL Behring human albumin solutions during the post-marketing phase, according to the MedDRA System Organ Class and Preferred Term level. As the post-marketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not possible to reliably estimate the frequency of these reactions. Hence the frequency category ‘not known (cannot be estimated from the available data)’ is used.

Table 1: List of adverse reactions

MedDRA System Organ Class	Adverse Reaction	Frequency
Immune system disorders	Hypersensitivity reactions (including anaphylaxis and shock)	Not known
Gastrointestinal disorders	Nausea	Not known
Skin and subcutaneous tissue disorders	Flush, urticaria	Not known
General disorders and administration site conditions	Fever	Not known

For safety information with respect to transmissible agents, see section 4.4.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Hypervolaemia may occur if the dosage and infusion rate are too high. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion) or increased blood pressure, raised central venous pressure and pulmonary oedema, the infusion should be stopped immediately and the patient's haemodynamic parameters carefully monitored.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Plasma expanders substitutes and plasma protein fractions.

ATC code: B05AA01

Mechanism of action

Human albumin accounts quantitatively for more than half of the total protein in the plasma and represents about 10% of the protein synthesis activity of the liver.

The most important physiological functions of albumin results from its contribution to oncotic pressure of the blood and transport function. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

5.2 Pharmacokinetic properties

Distribution

Under normal conditions, the total exchangeable albumin pool is 4–5 g/kg body weight, of which 40–45% is present intravascularly and 55–60% is in the extravascular space. Increased capillary permeability will alter albumin kinetics and abnormal distribution may occur in conditions such as severe burns or septic shock.

Elimination

Under normal conditions, the average half-life of albumin is about 19 days. The balance between synthesis and breakdown is normally achieved by feedback regulation. Elimination is predominantly intracellular and due to lysosome proteases.

In healthy subjects, less than 10% of infused albumin leaves the intravascular compartment during the first 2 hours following infusion. There is considerable individual variation in the effect on plasma volume. In some patients the plasma volume can remain increased for some hours. However, in critically ill patients, albumin can leak out of the vascular space in substantial amounts at an unpredictable rate.

5.3 Preclinical safety data

Human albumin is a normal constituent of human plasma and its action does not differ from that of physiological human albumin. Single dose toxicity testing in animals is of little relevance and does not permit the evaluation of toxic or lethal doses or of a dose-effect relationship. Repeated-dose toxicity testing is impracticable due to the development of antibodies to heterologous protein in animal models.

To date, human albumin has not been reported to be associated with embryofoetal toxicity, mutagenic, or carcinogenic potential. No signs of acute toxicity have been described in animal models.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acetyltryptophanate
Sodium octanoate
Sodium chloride
Water for injections

6.2 Incompatibilities

Alburex® 20 NZ must not be mixed with any other medicinal products, including whole blood, packed red cells, or other albumins, except those mentioned in section 6.6.

6.3 Shelf life

3 years

Stability after first opening:

Use in one patient on one occasion only. Alburex® 20 NZ contains no antimicrobial preservative. It must, therefore, be used immediately after opening the vial.

6.4 Special precautions for storage

Store below 25°C (Do not freeze).

Protect from light.

For storage conditions after first opening of the medicine, see section 6.3.

6.5 Nature and contents of container

Solution in a glass vial with a synthetic elastomer stopper.

Pack sizes:

One vial of 50 mL contains 10 g of human albumin.
One vial of 100 mL contains 20 g of human albumin.

6.6 Special precautions for disposal and other handling

Alburex® 20 NZ is administered intravenously.

Alburex® 20 NZ must not be diluted with water for injections as this may cause haemolysis in recipients.

If large volumes are administered, the product should be warmed to room or body temperature before use. Do not use if the solution has been frozen.

Alburex® 20 NZ can be diluted to a mildly hypooncotic solution to normal plasma (4–5% albumin) prior to administration, in the proportion of 1 mL of Alburex® 20 NZ to 4 mL of suitable crystalloid solution and administered by the usual intravenous technique.

Do not use solutions which are cloudy or have deposits. This may indicate that the protein is unstable or that the solution has become contaminated. The vial should be returned unopened to the New Zealand Blood Service.

Once the container has been opened, the contents should be used immediately.

Any unused solution must be discarded appropriately.

7 MEDICINE SCHEDULE

General Sale Medicine

NEW ZEALAND DATA SHEET

8 SPONSOR

CSL Behring (NZ) Ltd
PO Box 62590
Greenlane
Auckland 1546
New Zealand

For Medical/Technical Enquiries: TOLL FREE: 0800 640 677

For Customer Service Enquiries: TOLL FREE: 0800 841 532

customerservice@cslbehring.com.au

www.cslbehring.com.au

Manufacturer

CSL Behring (Australia) Pty Ltd
189–209 Camp Road
Broadmeadows
VIC 3047
Australia

Distributor

New Zealand Blood Service
71 Great South Road
Epsom
Auckland
New Zealand

9 DATE OF FIRST APPROVAL

01 June 2023

10 DATE OF REVISION OF THE TEXT

01 June 2023

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	New registration

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

Date of preparation

This leaflet was prepared on 18 May 2023

ALBUREX® 20 NZ

Human Albumin 20% (200g/L), solution for infusion

Manufactured from New Zealand plasma donations

ALBUMEX® 20 production has ceased.

The new Albumin 20% solution for infusion in New Zealand is ALBUREX® 20 NZ, 100mL.

COMPARISON

Differences	ALBUMEX® 20[1]		ALBUREX® 20 NZ[2]
Concentration	20% Albumin (200 g/L)		20% Albumin (200 g/L)
Presentation (vial) size	10 mL, 100 mL		100 mL only
Colour	Due to differences in the manufacturing processes albumin products can vary in colour; it is a clear, almost colourless, yellow, amber, or green liquid.		
Shelf life	48 months		36 months
Storage conditions	ALBUMEX® 20 10 mL vial Store 2-8°C (do not freeze)	ALBUMEX® 20 100 mL vial Store below 30°C (do not freeze)	ALBUREX® 20 NZ 100mL vial Store below 25°C (do not freeze)
Excipients	Sodium (48-100 mmol/L) Octanoate (32 mmol/L) Water for injections		Sodium acetyltryptophanate (16mmol/L) Sodium octanoate (16 mmol/L) Sodium chloride (NaCl is added to meet required sodium content) Water for injections
Osmolality	Normal osmolality of 130 mOsm/kg		Nominal osmolality of 258 mOsm/kg
pH	6.7 to 7.3		6.7 to 7.3
Oncotic pressure	Hyperoncotic and hypo-osmotic		Hyperoncotic
Chloride (Cl)	Not tested		Not tested
Sodium (Na)	48 to 100 mmol/L		140 mmol/L
Incompatibilities	ALBUMEX® 20 should not be mixed with protein hydrolysates, amino acid solutions, solutions containing alcohol, or solutions containing medicines that bind to albumin e.g. calcium channel blockers.		ALBUREX® 20 NZ must not be mixed with any other medicinal products, including whole blood, packed red cells, or other albumins.

SODIUM CONTENT

ALBUREX® 20 NZ contains approximately 3.2 mg sodium per mL of solution (140 mmol/L). For a 100 mL vial of ALBUREX® 20 NZ, this equates to approximately 320 mg of sodium. This should be noted when the product is used in patients requiring sodium restriction.

ADMINISTRATION AND INFUSION RATES

ALBUREX® 20 NZ should be administered by intravenous route only, using a vented infusion set.

ALBUREX® 20 NZ contains no antimicrobial preservative. It must be used immediately after opening the vial and completed within 4 hours.

ALBUREX® 20 NZ is supplied for a 'named-patient' only. Ensure the swing label issued by Blood Bank with the product is permanently retained in the 'named patient's' clinical records.

The infusion rate should be considered according to the individual patient clinical condition, especially the elderly and paediatric population.

The colloid osmotic effect of ALBUREX® 20 NZ is approximately four times that of blood plasma; patients should be monitored carefully to guard against circulatory overload and hyperhydration.

In plasma exchange the infusion rate should be adjusted to the rate of fluid removal.

Do not dilute ALBUREX® 20 NZ with water for injection as this may cause haemolysis.

Refer to the ALBUREX® 20 NZ Data Sheet for further information on compatibility and dilution.

MONITORING

Patients require regular monitoring to assess haemodynamic performance. This may include:

- blood pressure and pulse rate
- central venous pressure
- pulmonary artery wedge pressure
- urine output
- serum electrolytes
- haematocrit/haemoglobin

ADVERSE EFFECTS

Reactions are rare however human albumin solutions can cause mild reactions such as:

- flushing
- urticaria
- fever
- nausea

These reactions normally disappear rapidly when the infusion rate is slowed down, or the infusion is stopped. Severe allergic reactions such as anaphylactic shock are very rare. It is important to stop the infusion immediately, and seek medical review.

Any adverse event must be reported to the issuing Blood Bank.

References
1. Albumex® 20 (20%), solution for infusion - Data Sheet https://www.medsafe.govt.nz/profs/datasheet/a/Albumex20inf.pdf
2. Alburex® 20 NZ 20% (200g/L), solution for infusion - Data Sheet https://www.medsafe.govt.nz/profs/datasheet/a/alburex20NZinf.pdf

111116002

NZBLOOD