

Package leaflet: Information for the user

Zenalb 4.5 45 g/l solution for infusion human albumin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zenalb 4.5 is and what it is used for
2. What you need to know before you use Zenalb 4.5
3. How to use Zenalb 4.5
4. Possible side effects
5. How to store Zenalb 4.5
6. Contents of the pack and other information

1. What Zenalb 4.5 is and what it is used for

Zenalb 4.5 is a solution containing the active substance called human albumin (a protein found naturally in your blood which is needed for many different functions). Human albumin is obtained from blood plasma from screened donors selected from the USA.

Zenalb 4.5 is used to replace the blood or body fluids that you have lost because of bleeding, surgery, or kidney dialysis (blood “cleaning” by a machine). It contains a similar amount of albumin as normal blood.

This medicine is given by injection into a vein (intravenous infusion). It is only available on a doctor’s prescription.

2. What you need to know before you use Zenalb 4.5

Do not use Zenalb 4.5:

- if you are allergic to albumin or any of the other ingredients of Zenalb 4.5 (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before using Zenalb 4.5 if any of the following conditions applies to you:

- **allergic** or violent **reaction** to Zenalb 4.5 when injected. Treatment should be stopped immediately
- **blood problems**, especially severe **anaemia**, or a tendency to bleeding disorders
- **heart problems** where the heart is not pumping properly (heart failure)
- **high blood pressure** (hypertension)
- **increased blood volume** and associated complaints
- severe **kidney** problems or a chronic **liver** condition
- fluid accumulation in the **lungs**

You will need to be monitored closely during treatment and should be checked for dehydration and salt (electrolyte) balance in your body. If you start to feel ill, tell the doctor immediately, because the infusion rate may have to be altered or the treatment stopped.

Water should not be added to the Zenalb 4.5 solution as it may cause breaking down of some of your red blood cells.

Your doctor may recommend that you consider vaccination against hepatitis A and B if you regularly/repeatedly receive human plasma derived albumin.

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- the testing of each donation and pools of plasma for signs of virus/infections
- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

There are no reports of virus infections with albumin manufactured to European Pharmacopoeia requirements by established processes.

It is strongly recommended that every time you receive a dose of Zenalb 4.5 the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Children and adolescents

The listed warnings and precautions apply to both adults and children.

Other medicines and Zenalb 4.5

Other medicines are unlikely to affect your treatment with Zenalb 4.5. Tell your doctor if you are using, have recently used or might use any other medicines.

Zenalb 4.5 must not be diluted with water for injections. It may also be necessary to receive whole blood, plasma or red blood cells.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking Zenalb 4.5.

Driving and using machines

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

Zenalb 4.5 contains sodium

If you have been told that you have reduced kidney function or are on a potassium or sodium controlled diet, tell the doctor before he/she gives you the infusion.

This medicine contains 230 to 370 mg sodium (main component of cooking/table salt) in each 100 ml. This is equivalent to 11.5 to 18.5% of the recommended maximum daily dietary intake of salt for an adult.

3. How to use Zenalb 4.5

You will be given Zenalb 4.5 as an infusion (an injection given very slowly into a vein). It is unlikely that you will ever have to use Zenalb 4.5 yourself as infusion fluids are mainly given by a doctor or nurse.

The bottle will be warmed to room temperature before it is used. A thin plastic tube and connector will be inserted into your vein using a needle; the needle will be removed and the connector will be attached to a plastic tube. The bottle of medicine will be attached to the other end of the tube and hung in the plastic sling above you. The medicine will pass down the tube slowly, through a filter and into your body through the thin plastic tube.

How much you will be given

Your doctor or nurse will calculate how much Zenalb 4.5 to give you and how often you should receive it. The amount given will depend on your individual needs.

During and after treatment with Zenalb 4.5, your doctor may check any or all of the following:

- how well the medicine is working by taking your pulse or heart rate
- your blood pressure
- the pressure inside your heart or lungs by placing a very thin tube into your vein or artery
- your heart and breathing will be checked regularly, particularly if you are elderly or very young
- blood tests may be carried out to check when the right amounts of protein, sodium and potassium are present and treatment can stop

Use in children

The amount given will depend on the age of your child. Your doctor will take this into account when calculating the amount to give.

If you experience headache, difficulty in breathing, jugular vein congestion (signs that your heart is becoming overloaded), or increased blood pressure, raised venous pressure or pulmonary oedema, the infusion will be stopped immediately.

This medicine will not interfere with blood tests that are carried out after it has been given.

If you are given more Zenalb 4.5 than you should

If you receive more Zenalb 4.5 than you should, you may experience:

- high blood pressure, difficulty in breathing (particularly when lying down) and high pressure inside your heart, which your doctor can measure.

In the unlikely event that too much medicine is given, the infusion will be stopped immediately and your doctor may give you treatment to remove the excess fluid.

If you feel unwell afterwards or have any discomfort, tell your doctor.

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

4. Possible side effects

Like all medicines, Zenalb 4.5 can cause side effects, although not everybody gets them.

The following side effects may occur infrequently and are usually mild:

- feeling sick
- flushing
- feeling feverish
- itchy, raised bumps on the skin
- shaking of the body (rigors)
- high blood pressure (hypertension)
- low blood pressure (hypotension)
- feeling cold
- increased heart rate (tachycardia)
- tremor
- shortness of breath

- chest tightness
- wheezing
- noisy breathing from throat (stridor)
- dizziness

If you feel unwell, you must tell your doctor immediately.

Some people may have an allergic reaction ranging from a mild skin rash to more serious cases of shock (when your blood pressure falls dangerously low). Symptoms of this are:

- dizziness
- sweating
- cold, clammy skin.

Your doctor will stop the infusion and treat the allergic reaction if this happens.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zenalb 4.5

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after “EXP”.

The expiry date refers to the last day of that month.

Store between 2°C and 25°C. Do not freeze. Use within 3 hours of opening the bottle.

Do not use this medicine if you notice the solution is cloudy or has deposits.

Keep it in its original carton to protect it from light.

Your doctor will discard any unused solution. Medicines should not be disposed of via wastewater or household waste, to help protect the environment.

6. Contents of the pack and other information

What Zenalb 4.5 contains

- The active substance is human albumin. Zenalb 4.5 is a solution containing 45 g/l of total protein, of which at least 95% is human albumin.
- The other ingredients are sodium octanoate, sodium chloride, sodium hydroxide (for pH adjustment), acetic acid (for pH adjustment) and water for injections.

What Zenalb 4.5 looks like and contents of the pack

Zenalb 4.5 is a clear, almost colourless yellow, amber or green thick (viscous) liquid in a glass bottle with a rubber stopper and tamper evident flip-off cap.

Zenalb 4.5 is available in 50 ml, 100 ml, 250 ml and 500 ml pack sizes, with a sling to hold the bottle during infusion.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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