

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### ZENBUMIN 20 200 g/l SOLUTION FOR INFUSION

#### HUMAN ALBUMIN SOLUTION

**PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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#### **1. WHAT ZENBUMIN 20 IS AND WHAT IT IS USED FOR**

Zenbumin 20 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.

Zenbumin 20 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 four times the amount of albumin as normal blood.

The product is given by injection into a vein (intravenous infusion) either undiluted or in a solution containing 5% glucose or 0.9% sodium chloride. It is only available on a doctor’s prescription.

This medicine is also suitable for premature babies and patients on kidney dialysis as it contains only very small quantities of aluminium.

#### **2. BEFORE YOU ARE GIVEN ZENBUMIN 20**

**Do not allow Zenbumin 20 to be given to you if you:**

- are allergic to albumin or any of the other ingredients of Zenbumin 20 (*see Section 6 and end of Section 2 Important information about some of the ingredients of Zenbumin 20*).

#### **Take special care with Zenbumin 20**

You must tell your doctor before receiving Zenbumin 20 if any of the following conditions applies to you:

- **allergic** or violent **reaction** to Zenbumin 20 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**
- **elderly**
- a young **child**
- receiving **regular or repeated infusions** of Zenbumin 20. You may need to have a vaccination for hepatitis A and B

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, then tell the doctor immediately, because the infusion rate may have to be altered or the treatment stopped.

Water should not be added to the Zenbumin 20 solution as it may cause breaking down of some of your red blood cells.

### **Taking other medicines**

Other medicines are unlikely to affect your treatment with Zenbumin 20. However, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Zenbumin 20 can be diluted with 5% glucose or 0.9% sodium chloride, but must not be diluted with water for injections. It may also be necessary to receive whole blood, plasma or red blood cells.

### **Pregnancy and breast-feeding**

Tell your doctor before receiving Zenbumin 20 if you are pregnant, likely to become pregnant or are breast-feeding.

### **Driving and using machines**

There are no restrictions on driving or using machines after being treated with Zenbumin 20.

### **Important information about some of the ingredients of Zenbumin 20**

Sodium is an ingredient in this product.

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

## **3. HOW YOU WILL BE GIVEN ZENBUMIN 20**

You will be given Zenbumin 20 as an infusion (an injection given very slowly into a vein). It is unlikely that you will ever have to use Zenbumin 20 yourself; 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 Zenbumin 20 to give you and how often you should receive it. The amount given will depend on your individual needs.

During and after treatment with Zenbumin 20, 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 are present and treatment can stop

*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.

**The usual dose for infusion** will be decided by your doctor depending on your condition and your response to treatment.

Your medicine can be diluted with 5% glucose or 0.9% sodium chloride by your doctor but no other medicine should be added to the liquid before it is given.

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 ZENBUMIN 20 than you should**

If you receive more Zenbumin 20 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.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Zenbumin 20 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.

**If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.**

#### **Please note**

Although no patients have developed virus infections from human albumin solutions, the possibility of infection from using medicines made from human blood cannot be totally ruled out. This warning includes known, unknown and new viruses and some other germs. Several different steps have been taken to make this possibility very unlikely. These include the careful selection of donors and testing of the plasma they provide for specific types of infection.

The method used to produce the medicine from their blood plasma includes steps to kill or remove viruses such as HIV, hepatitis A, hepatitis B, and hepatitis C.

#### **Please remember:**

The expected benefits of your medicine will usually be greater than the risks of suffering any harmful side effects.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist 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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE ZENBUMIN 20**

Keep Zenbumin 20 out of the reach and sight of children.

The medicine should be stored in a fridge or in a cool place between 2°C and 25°C. Do not freeze. Keep it in its original carton to protect it from light.

#### **Note to doctor or nurse:**

- Do not use Zenbumin 20 if you notice the solution is cloudy or has deposits.
- Do not use Zenbumin 20 after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Use within 3 hours of opening as there is no preservative in Zenbumin 20.

#### **Disposal**

Your doctor will discard any unused solution.

Medicines should not be disposed of via wastewater or household waste, to help protect the environment.

### **6. FURTHER INFORMATION**

#### **What ZENBUMIN 20 contains**

The **active** substance is at least 95% human albumin (200g/litre of protein) obtained from blood from screened donors.

These donors are selected from the USA.

The **other** ingredients are sodium, chloride, acetyltryptophanate (as a stabiliser), octanoate (as a stabiliser) and water for injection.

*For **sodium** see end of Section 2: Important information about some of the ingredients of Zenbumin 20.*

**What ZENBUMIN 20 looks like and contents of the pack**

Zenbumin 20 is a sterile, almost colourless yellow or green thick (viscous) liquid in a glass bottle with a rubber stopper and sealed cap.

This product is available in 50 ml or 100 ml sizes.

**Marketing Authorisation Holder, and manufacturer**

Bio Products Laboratory Limited,  
Elstree, WD6 3BX  
United Kingdom.

**Marketing Authorisation Number**

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For further information or if you have any questions about the use of this product, please contact BPL via the Marketing Department at the address above or through [info@bpl.co.uk](mailto:info@bpl.co.uk).

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