PATIENT INFORMATION LEAFLET FOR
ALBUMIN HUMAN 20 % OCTAPHARMA®

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ALBUMIN HUMAN 20 % OCTAPHARMA® (Solution for Intravenous infusion)

Read all of this leaflet carefully before you are given ALBUMIN HUMAN 20 % OCTAPHARMA®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ALBUMIN HUMAN 20 % OCTAPHARMA®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT ALBUMIN HUMAN 20 % OCTAPHARMA® CONTAINS

- The active ingredient is Human albumin 200 g (20 %) per 1 000 ml solution: (200 mg plasma protein per ml solution of which at least 96 % is human albumin)
- The other ingredients are:

Caprylic acid	12,8 to 19,2 mmol
N-acetyl-DL-tryptophan	12,8 to 19,2 mmol
Potassium	≤ 10 mmol
Sodium	144 to 160 mmol

Water for Injections	to 1 000 ml
The limit for Aluminium	not more than 200 µg/l

ALBUMIN HUMAN 20 % OCTAPHARMA® contains no antimicrobial agent or preservative. The pH of the solution is between 6,7 and 7,3.

WHAT ALBUMIN HUMAN 20 % OCTAPHARMA® IS USED FOR

Human albumin is a normal part of human plasma. Albumin expands and regulates the volume of circulating blood.

Human albumin accounts for more than half of the total protein in the blood.

Albumin stabilises circulating blood volume and is necessary for transporting different proteins in the body.

When there has been an abnormal decrease in the volume of blood in your body, for example due to a wound or an injury**, ALBUMIN HUMAN 20 % OCTAPHARMA®** is used to restore your blood volume.

BEFORE YOU ARE GIVEN ALBUMIN HUMAN 20 % OCTAPHARMA®

You should not be given ALBUMIN HUMAN 20 % OCTAPHARMA®:

- If you are allergic to albumin containing preparations including **ALBUMIN HUMAN 20 % OCTAPHARMA®**
- If you are allergic to any of the other ingredients in **ALBUMIN HUMAN 20 % OCTAPHARMA®**

Tell your doctor or healthcare professional before receiving the injection if:

- You are on a sodium (salt) controlled diet.
- You are on a potassium controlled diet.
- You have kidney impairment.

Special care should be taken with ALBUMIN HUMAN 20 % OCTAPHARMA®

if you suffer from conditions where:

an excessive build-up of fluid or a decrease of certain important blood elements could represent a special risk for you.

Examples of such conditions are:

- Decompensated cardiac insufficiency (when the heart is unable to maintain adequate blood circulation)
- Hypertension (high blood pressure)
- Oesophageal varices (enlargement of the vein in the lower part of the gullet)
- Pulmonary oedema (water on the lungs)
- Haemorrhagic diathesis (a disease that causes bleeding)
- Severe Anaemia (for example severe iron deficiency in the blood)
- Too little urine output

Further Special Care should be taken with ALBUMIN HUMAN 20 % OCTAPHARMA®:

- If an allergic or anaphylactic-type (skin rash or hives) reaction occurs. Your medical practitioner will stop the infusion immediately and treat you accordingly.
- In case of shock (excessive loss of body fluid). Your medical practitioner will apply the correct current treatment for shock.
- If you have experienced a trauma to the brain.

- To ensure that you receive adequate fluid during treatment. You should however also be monitored carefully to guard against too much circulatory fluid.
- To monitor your salt, sugar and mineral balance (see HOW TO RECEIVE **ALBUMIN HUMAN 20 % OCTAPHARMA®**) and proper steps should be taken to restore or maintain this balance.
- When you are given large volumes of **ALBUMIN HUMAN 20 % OCTAPHARMA®,** your medical practitioner should monitor your blood clotting capability and red blood cell count and ensure that you receive sufficient other important blood elements when necessary.
- To ensure that at the first signs of increased blood volume (headache, shortness of breath, jugular or neck vein obstruction), or increased blood pressure, and water on the lungs, your infusion is stopped immediately.

When medicines are prepared from human blood or plasma certain measures are put in place to reduce the risk of infections being passed on to patients.

Despite these measures the possibility of passing on infections cannot be totally excluded.

There have been no reports of virus infections with **ALBUMIN HUMAN 20 % OCTAPHARMA®** as donors are carefully selected and the manufacturing is such that it can inactivate or remove viruses.

It is strongly recommended that, every time you receive **ALBUMIN HUMAN 20 % OCTAPHARMA®** the name and batch number of the product are recorded.

Receiving ALBUMIN HUMAN 20 % OCTAPHARMA® with food and drink:

Your doctor will prescribe the food and drink that you may consume

Pregnancy and Breastfeeding:

The safety of **ALBUMIN HUMAN 20 % OCTAPHARMA®** for use in pregnancy and breast feeding has not been established. However during clinical use of albumin there has been no evidence of harmful effects during pregnancy, or to the baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Driving and using machinery:

ALBUMIN HUMAN 20 % OCTAPHARMA® does not impair the ability to drive and use machines.

Important information about some of the ingredients of ALBUMIN HUMAN 20 % OCTAPHARMA®:

ALBUMIN HUMAN 20 % OCTAPHARMA® contains small amounts of sodium chloride (salt) and potassium. Please inform your doctor or other healthcare professional if you are on a low salt diet or you need to restrict your potassium intake. (see **Special care should be taken with ALBUMIN HUMAN 20 % OCTAPHARMA®**)

ALBUMIN HUMAN 20 % OCTAPHARMA® contains no antimicrobials or preservatives

Using other medicines with ALBUMIN HUMAN 20 % OCTAPHARMA®:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines)

No specific interactions of **ALBUMIN HUMAN 20 % OCTAPHARMA®** with other medicinal products are known.

HOW TO RECEIVE ALBUMIN HUMAN 20 % OCTAPHARMA®

ALBUMIN HUMAN 20 % OCTAPHARMA® is given as an intravenous infusion**.**

You will not be expected to give yourself **ALBUMIN HUMAN 20 % OCTAPHARMA®.** It will be given to you by a person qualified to do so.

If you receive more ALBUMIN HUMAN 20 % OCTAPHARMA® than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage. However in the event of overdosage your doctor will manage the overdosage.

Do not mix **ALBUMIN HUMAN 20 % OCTAPHARMA®** infusion with other medicines, whole blood or packed cells before administration. This will cause the preparation to become unstable.

Do not dilute **ALBUMIN HUMAN 20 % OCTAPHARMA®** with water for injections. This may cause the destruction of blood cells in the person receiving the infusion.

POSSIBLE SIDE EFFECTS

ALBUMIN HUMAN 20 % OCTAPHARMA® can have side effects.

These reactions normally disappear rapidly when the injection rate is slowed down or stopped. If you experience severe reactions, the infusion will be stopped by your doctor and correct treatment will be started.

The following side effects have been observed for **ALBUMIN HUMAN 20 % OCTAPHARMA®:**

If any of the following happens tell your doctor immediately or seek medical assistance immediately:

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **ALBUMIN HUMAN 20 % OCTAPHARMA®.** You may need urgent medical attention – your healthcare practitioner should take appropriate steps to treat you.

These side effects occur less frequently with **ALBUMIN HUMAN 20 % OCTAPHARMA®.**

- Anaphylactic shock (swelling of the hands, feet, ankles, face, lips or throat that may cause difficulty in swallowing or breathing).
- Rash or itchiness

Tell your doctor immediately if you notice any of the following:

These are serious side effects. You may need urgent medical attention.

These side effects occur less frequently with **ALBUMIN HUMAN 20 % OCTAPHARMA®.**

- Changes in the way your heart beats, for examle, if you notice it beating faster
- Difficulty breathing

Tell your doctor if you notice any of the following:

These side effects occur less frequently with **ALBUMIN HUMAN 20 % OCTAPHARMA®.**

- Confusion
- Headache
- Low or high blood pressure
- Flushing (heat sensation) or increased sweating

- Nausea (feeling sick) or vomiting
- Increased saliva
- Fever
- Stiffness or muscle cramps

Not all side effects reported for **ALBUMIN HUMAN 20 % OCTAPHARMA®** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given this medicine please consult your doctor, pharmacist or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ALBUMIN HUMAN 20 % OCTAPHARMA®

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store and transport at 2 ºC to 25 ºC. Protect from light

DO NOT FREEZE.

Store in the original container. Keep the container in the outer carton.

Once the infusion container has been opened use the content immediately and return any unused part to your pharmacist.

Do not use after the expiry date stated on the bottle.

Do not use solutions which are cloudy or have deposits

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ALBUMIN HUMAN 20 % OCTAPHARMA®

50 ml of solution in infusion bottle with rubber stopper.
Pack of 1 and packs of 10.

100 ml of solution in infusion bottle with rubber stopper.

Pack of 1 and packs of 10.

IDENTIFICATION OF ALBUMIN HUMAN 20 % OCTAPHARMA®

Clear, slightly viscous liquid; almost colourless, yellow, amber or green.

Free of visible particles.

REGISTRATION NUMBER

36/30.3/0057

NAME AND ADDRESS OF REGISTRATION HOLDER

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