PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

OCTALBIN 25%

Albumin (Human)
Solution for Infusion; 250 mg/mL
Intravenous Use

Ph. Eur.

Plasma Substitute and Plasma Protein Fractions
ATC code: B05AA01

Manufactured by:
Octapharma Pharmazeutika Produktionsges m.b.H.
Oberlaaer Strasse 235
A-1100 Vienna, Austria

Date of Initial Authorization:
MAY 06, 2005

Date of Revision:
SEP 20, 2024

Manufactured for:
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Submission Control Number: 285986

RECENT MAJOR LABEL CHANGES

Not applicable

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Sections or subsections that are not applicable at the time of authorization are not listed.

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OCTALBIN 25%

Albumin (Human) 250 mg/mL

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Octalbin 25% (Albumin (Human) 250 mg/mL) is indicated for:

- 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, according to current therapeutic recommendations.

1.1 Pediatrics

Pediatrics (< 12 years of age): Data on the use of Octalbin 25% in children including premature babies are very limited. The product should only be administered to these individuals if the likely benefits clearly outweigh potential risks.

1.2 Geriatrics

Geriatrics (>65 yeas of age): No subgroup analysis was performed and therefore no safety or tolerability data regarding a geriatric population can be presented.

2 CONTRAINDICATIONS

Octalbin 25% is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see **6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.**

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions
This product is prepared from large pools of human plasma, which may contain the causative agents of hepatitis and other viral diseases. The physician should discuss the risks and benefits of this product with the patient before prescribing or administering to the patient (see **7. WARNINGS AND PRECAUTIONS** – General).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Human albumin should always be directly administered by the intravenous route. Octalbin 25% may also be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride).

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

4.2 Recommended Dose and Dosage Adjustment

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.

If human albumin 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

This product is suitable for premature infants and dialysis patients.

The infusion rate should be adjusted according to the individual circumstances and the indication, but should normally not exceed 1 to 2 mL/minute.

In plasma exchange the infusion rate may be higher and should be adjusted to the rate of removal.

4.4 Administration

The solution should be directly administered by the intravenous route or it can also be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride). The product should be warmed to room or body temperature before use.

The solution should be clear or slightly opalescent. 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.

Once the infusion container has been opened the content should be used immediately. Any unused solution should be disposed of in accordance with local requirements.

Do not use after expiry date given on the label.

Solutions which have been frozen should not be used.

Do not begin administration more than four hours after the container has been entered.

Vials which are cracked or have been previously entered or damaged should not be used, as this may have allowed the entry of microorganisms.

The 25% solution contains no preservative.

Incompatibilities

Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

4.5 Missed Dose

Not applicable because Octalbin 25% is administered in a hospital setting by health care professionals.

5 OVERDOSAGE

Hypervolaemia may occur if the dosage and rate of infusion 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 management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of biologic products, including biosimilars, health professionals should recognise the importance of recording both the brand name and the non-proprietary (active ingredient) name as well as other product-specific identifiers such as the Drug Identification Number (DIN) and the batch/lot number of the product supplied.

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength / Composition	Non-medicinal Ingredients	
Intravenous use	Solution for infusion Each mL contains 250 mg protein, of which ≥ 96% is human albumin	1000 mL solution contain: Aluminium Caprylic acid N-acetyl-DL-tryptophan Potassium Sodium Water for injections	 max. 200 µg max. 21 mmol max. 21 mmol max. 2.0 mmol 142.5-157.5 mmol ad 1000 mL

Octalbin 25% is human albumin from human plasma source and it contains 250 mg/mL of protein, of which at least 96% is human albumin.

Octalbin 25% contains no preservative. Octalbin 25% is a clear, slightly viscous liquid; it is almost colorless or slightly yellow or green.

Nature and contents of container

Glass bottles are made of glass quality type II (Ph.Eur.) and are closed with bromobutyl rubber stoppers quality type I (Ph.Eur.).

Package sizes:

Single pack:
1 infusion bottle with 50 mL
1 infusion bottle with 100 mL

Multiple pack:
10 x 1 infusion bottle with 50 mL
10 x 1 infusion bottle with 100 mL

7 WARNINGS AND PRECAUTIONS

Please see **3 SERIOUS WARNINGS AND PRECAUTIONS BOX.**

This product is prepared from large pools of human plasma. Thus, there is a possibility it may contain causative agents of viral or other undetermined diseases.

General

Standard measure to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

Albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extreme remote risk for transmission of viral diseases. A theoretical transmission of Creutzfeldt-Jakob Disease (CJD), including variant Creutzfeldt-Jakob Disease (vCJD), also is considered remote. No cases of transmission of viral diseases or CJD, including vCJD, have ever been identified for albumin.

Albumin manufactured to European Pharmacopoeia specifications by established processes has a reassuring viral safety record.

The physician should discuss the risks and benefits of the product with the patient, before prescribing or administering to the patient.

If allergic or anaphylactic-type reactions occur, the infusion should be stopped immediately and appropriate treatment instituted. In case of shock, the current medical standards for shock-treatment should be observed.

Albumin solutions must not be diluted with water for injection as this may cause haemolysis in recipients.

Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. In the interest of the patient, it is recommended that, whenever possible, every time that Octalbin 25% (Albumin (Human) 250 mg/mL) is administered to them, the name and batch number of the product is recorded.

Albumin solutions must not be used in patients at high risk of developing circulatory overload (e.g. congestive cardiac failure, renal insufficiency) or severe deficiency of oxygen carrying capacity (severe anemia).

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 25% 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.

Hypervolaemia may occur if the dosage and rate of infusion are not adjusted to the patients 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.

20-25% Human albumin solutions are relatively low in electrolytes compared to the 4-5% human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored (see section **4 DOSAGE AND ADMINISTRATION**) and appropriate steps taken to restore or maintain the electrolyte balance.

Octalbin 25% contains 3.28-3.62 mg sodium and 0.078 mg potassium per mL solution (See **6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING**), which should be taken into consideration for patients on a controlled sodium or potassium intake.

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).

7.1 Special Populations

7.1.1 Pregnant Women

The safety of Octalbin 25% for use in human pregnancy has not been established in controlled clinical trials. While it is not known if it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity, it should be given to a pregnant woman only if clearly needed.
No animal reproduction studies have been conducted with Octalbin 25%. However, human albumin is a normal constituent of human blood.

7.1.2 Breast-feeding

There is no information regarding the presence of Octalbin 25% in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Octalbin 25% and any potential adverse effects on the breastfed infant from Octalbin 25% or from the underlying maternal condition.

7.1.3 Pediatrics

Pediatrics (< 12 years of age):

Data on the use of Octalbin 25% in children including premature babies are very limited. The product should only be administered to these individuals if the likely benefits clearly outweigh potential risks.

7.1.4 Geriatrics

Geriatrics (> 65 years of age):

No subgroup analysis was performed and therefore no safety or tolerability data regarding a geriatric population can be presented.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Adverse reactions for Octalbin 25% are rare. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.

8.2 Clinical Trial Adverse Reactions

Not applicable.

8.3 Less Common Clinical Trial Adverse Reactions

Not applicable.

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data

There were no particular issues raised for any laboratory parameters in any of the published studies.

8.5 Post-Market Adverse Reactions

The following adverse reactions have been observed for human albumin during the post-marketing phase. Therefore, these reactions can also be expected for Octalbin 25%.

Table 2 – adverse reactions for human albumin observed during post-marketing phase

System Organ Class	Rare (>1/10,000, <1/1,000)	Very rare (<1/10,000)
Immune system disorders	hypersensitivity	anaphylactic shock anaphylactic reaction
Psychiatric disorders		confusional state
Nervous system disorders		headache
Cardiac disorders		tachycardia bradycardia
Vascular disorders	hypotension	hypertension flushing
Respiratory, thoracic and mediastinal disorders		dyspnoea
Gastrointestinal disorders		nausea
Skin and subcutaneous tissue disorders		urticaria angioneurotic edema rash erythematous hyperhidrosis pruritus
General disorders and administration site conditions		pyrexia chills

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

No specific interactions of human albumin with other medicinal products are known.
Human albumin solution must not be mixed with other medicinal products, whole blood and packed red cells.

9.3 Drug-Behavioural Interactions

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

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Albumin is the predominant product of hepatic protein synthesis and one of the more abundant plasma proteins. Among its multiple physiologic roles that include binding and transport of molecules, free radical scavenging, inhibition of platelet function and antithrombotic effects, and effects on the capillary membrane permeability, human albumin plays an essential part in the generation of colloid-oncotic pressure.

10.2 Pharmacodynamics

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 human albumin result 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.

10.3 Pharmacokinetics

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% 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.
Under normal conditions, the average half-life of albumin is about 19 days. The balance between synthesis and breakdown is normally achieved by feed-back 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.

11 STORAGE, STABILITY AND DISPOSAL

Special precautions for storage:

Store and transport at +2 °C to +25 °C.
Store in the original container in order to protect from light.

Do not use after expiry date.

Do not freeze.

Keep out of the reach of children!

Any unused product or waste material should be disposed of in accordance with local requirements.

12 SPECIAL HANDLING INSTRUCTIONS

Please see section **4.4 Administration.**

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Octalbin 25%

Chemical name: Human Albumin

Molecular formula and molecular mass: not applicable

Structural formula: not applicable

Physicochemical properties: Human serum albumin (HSA) is a monomeric protein, made up only of amino acids without prosthetic or carbohydrate groups. Albumin has a high percentage of ionic amino acids, glutamic acid and lysine, which confer a relatively high solubility to the protein.

Product Characteristics

Octalbin 25% is a solution containing plasma proteins in a concentration of 250 mg/mL with a content of human albumin of at least 96%. It is manufactured according to the cold ethanol fractionation method.

Viral Inactivation

The plasma used for the manufacture of Octalbin 25% is obtained from collection centres that are inspected by national health authorities and audited by Octapharma.
The product is manufactured by the cold ethanol fractionation process followed by ultra- and diafiltration. The manufacturing process includes final container pasteurisation and an additional bulk pasteurisation at 60 ± 0.5°C for 10 – 11 hours. The Octalbin 25% manufacturing process provides a significant viral reduction in in vitro studies. These reductions are achieved through a combination of process steps including cold ethanol fractionation and final container pasteurisation.

14 CLINICAL TRIALS

Not applicable.

16 NON-CLINICAL TOXICOLOGY

No long-term animal studies have been performed to evaluate carcinogenic or mutagenic potential or whether Octalbin 25% affects fertility in males or females.

Albumin is a normal constituent of the human organism. In animals, single dose toxicity testing is of no relevance, since the high doses required would result in Albumin overload. Repeated dose toxicity testing, and embryo-fetal toxicity studies with albumin preparations are impracticable due to the induction of, and the interference with antibodies. Effects of the preparation on the immune system of new-born animals have not been studied.

Since the clinical experience does not provide any evidence of tumorigenic or mutagenic effects of Albumin, experimental studies, particularly in heterologous species, are not considered to be necessary.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

OCTALBIN 25%

Albumin (Human) 250 mg/mL

Read this carefully before you start taking **Octalbin 25%** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Octalbin 25%**.

Serious Warnings and Precautions

This product is made from human plasma, which may contain infectious agents, such as viruses that cause hepatitis and other viral diseases. Your doctor should discuss the risks and benefits of this product with you before giving you this product.

What is Octalbin 25% used for?

- The product is given to patients to restore and maintain circulating blood volume where a deficiency in volume has been demonstrated.

How does Octalbin 25% work?

The main task of albumin is the maintenance of the colloidal osmotic (= oncotic) pressure. This type of pressure arises from the ability of albumin to bind to water. The presence of albumin in the plasma ensures that the liquid remains within the vessels and does not diffuse into the tissue.

Albumin is also a transport protein. It binds substances produced by the body, such as hormones or fatty acids as well as drugs such as penicillin, and transports them around the body.

Albumin also acts as a kind of protein reserve. If the body requires building blocks for the repair of large wounds or in inflammations, albumin can be broken down, and the breakdown products can be used as building blocks for other proteins.

What are the ingredients in Octalbin 25%?

Medicinal ingredients: Human albumin from human plasma source

Non-medicinal ingredients: Sodium, Potassium, N-acetyl-DL-tryptophan, Caprylic acid, Aluminium, Water for injections

Octalbin 25% comes in the following dosage forms:

Octalbin 25% is a 250 mg/mL solution for intravenous infusion and comes in the following dosage forms:
1 infusion bottle with 50 mL
1 infusion bottle with 100 mL

Do not use Octalbin 25% if:

Octalbin 25% should not be used if you are hypersensitive to albumin preparations or any of the other ingredients or component of the container of the product

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Octalbin 25%. Talk about any health conditions or problems you may

have, including if you: Are allergic to the active substance, any of the nonmedicinal ingredients or component of the container.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Octalbin 25%:

No interactions of human albumin with other products are known so far. However, Octalbin 25% solution should not be mixed in the same injection with other drugs, whole blood or packed red cells.

How to take Octalbin 25%:

Octalbin 25% will be given to you by a healthcare professional in a healthcare setting.

Usual dose:

As dosage and treatment duration depend on your clinical situation, your physician will decide on your treatment on an individual basis.

Overdose:

If the dosage and rate of infusion are too high, you may develop headache, high blood pressure and discomfort breathing. The infusion should be stopped immediately and your doctor will decide if any other treatment is necessary.

If you think you, or a person you are caring for, have taken too much Octalbin 25%, contact a health care professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable because Octalbin 25% is administered in a hospital setting by health care professionals.

What are possible side effects from using Octalbin 25%?

These are not all the possible side effects you may have when taking Octalbin 25%. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
RARE			
low blood pressure			X
allergic reaction			X
VERY RARE			
anaphylactic reaction			X
anaphylactic shock			X
confusional state			X
headache	X		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
rapid heartbeat			X
slow heart rate			X
high blood pressure			X
flushing			X
difficulty breathing			X
feeling sick	X		
itchy rash			X
angioneurotic edema			X
rash erythematous			X
itching	X		
excessive sweating	X		
fever			X
chills			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store and transport at +2 °C to +25 °C.
Store in the original container in order to protect from light.
Do not use after expiry date. Do not freeze.
Keep out of the reach and sight of children.

If you want more information about Octalbin 25%:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website http://www.octapharma.ca or by calling 1-888-438-0488.

This leaflet was prepared by Octapharma Pharmazeutika Produktionsges.m.b.H

Last revised: September 12, 2024