PACKAGE LEAFLET: INFORMATION FOR THE USER

ALBUNORM 20%

200 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 pharmacist.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT ALBUNORM 20% IS AND WHAT IT IS USED FOR

Albunorm 20% belongs to the pharmacotherapeutic group: blood substitutes and plasma protein fractions.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ALBUNORM 20%

Do not use Albunorm 20%

- if you are allergic to human albumin preparations or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Albunorm 20%.

Take special care with Albunorm 20%

- if you are at special risk from increased blood volume e.g. in case of severe heart disorders, high blood pressure, dilated veins of the oesophagus, fluid in the lung, bleeding disorders, severely lowered red blood cell count or without urine output.
- when there are signs for increased blood volume (headache, breathing disorder, jugular vein congestion) or increased blood pressure. The infusion should be stopped immediately.
- when there are signs of an allergic reaction. The infusion should be stopped immediately.
- when it is used in patients with severe traumatic brain injury.

Virus safety

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
- testing of each donation and pools of plasma for signs of virus/infections
- steps included by the manufacturers 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 specifications by established processes.

It is strongly recommended that every time you receive a dose of Albunorm 20% the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Albunorm 20%

No interactions of human albumin with other products are known so far. However, Albunorm 20% solution should not be mixed in the same infusion with other drugs, whole blood or packed red cells. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Human albumin is a normal constituent of human blood. No harmful effects are known when this product is used during pregnancy or breast-feeding. Particular care should be taken to adjust blood volume in pregnant women.

Ask your doctor for advice before taking any medicine.

Driving and using machines

There are no indications that human albumin impairs the ability to drive or to operate machines.

Albunorm 20% contains sodium

This medicine contains 331 - 368 mg sodium (main component of cooking/table salt) per 100 ml albumin solution. This is equivalent to up to 18.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO USE ALBUNORM 20%

Albunorm 20% is ready for use as an infusion ("drip") into a vein. The dosage and infusion rate (how quickly you are given albumin into a vein) will depend on your particular condition. Your doctor will decide what treatment is best for you.

Instructions

- The product should be brought to room or body temperature before use.
- The solution should be clear and should not have a deposit.
- Any unused solution should be discarded.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use more Albunorm 20% than you should

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects after infusion of human albumin are rare and they normally disappear when the infusion-rate is slowed down or stopped.

Rare: affects 1 to 10 users in 10,000:

Flush, urticaria, fever and nausea.

Very rare: affects less than 1 user in 10,000:

Shock due to hypersensitivity reaction.

Frequency not known: cannot be estimated from the available data:

Confusional state; headache; increased or decreased heart rate; high blood pressure or low blood pressure; heat sensation; shortage of breath; nausea; nettle rash; swelling around eyes, nose, mouth; rash; increased sweating; fever; chills.

Reporting of suspected adverse reactions

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

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 ALBUNORM 20%

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

Do not use this medicine after expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light. Do not freeze.

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

The solution should be clear or slightly opalescent. Do not use solutions which are cloudy or have deposits.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Albunorm 20% contains

- The active substance is 200 g/l human albumin derived from human plasma (bottle of 50, 100 ml).
- The other ingredients are sodium chloride, N-Acetyl-DL-tryptophan, caprylic acid and water for injections.

What Albunorm 20% looks like and contents of the pack:

Albunorm 20% is a solution for infusion in a bottle (50 ml - pack size of 1 and 10)
Albunorm 20% is a solution for infusion in a bottle (100 ml - pack size of 1 and 10)

The solution is clear, yellow, amber or green.

Not all pack sizes may be marketed in all countries.

Marketing Authorisation Holder and Manufacturers:

Octapharma Ltd.
Glassworks House
32 Shudehill
Manchester M4 1EZ
United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:
Albunorm: Czech Republic, Denmark, Italy
Albunorm 20%: Belgium, Bulgaria, Cyprus, Germany, Ireland, Iceland, Luxemburg, Malta, Netherlands, Poland, Portugal, Slovak Republic, Spain, United Kingdom
Albunorm 200 g/l: Austria, Estonia, Finland, France, Hungary, Latvia, Lithuania, Norway, Romania, Sweden, Slovenia

Manufacturers:

Octapharma Pharmazeutika, Produktionsges.m.b.H., Oberlaaerstrasse 235, 1100 Vienna, Austria

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