SCHEDULING STATUS: **S4**

Albusol® 4 %

0,04 g/ml, solution for infusion

Human albumin

Sugar free

Read all of this leaflet carefully before you are given Albusol 4 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Albusol 4 % 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 is in this leaflet:

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

1. What Albusol 4 % is and what it is used for

Albusol 4 % belongs to the blood substitutes and plasma protein fractions group of medicines.

It is very important that the right amount of fluid is circulating in your blood stream. If you lose a lot of fluid, you will need to have extra fluid put back into your body to replace it. Albusol 4 % has a similar amount of the main protein in the fluid part of your blood (plasma) and can therefore be used to bring the volume of fluid in your blood stream back to normal.

Some examples of conditions where low blood volume could occur are:

- Shock associated with blood loss, injuries and surgery
- Burns
- Loss of proteins in the body due to certain disorders that affect their absorption, production and breakdown
- Removal of fluid from the abdomen in patients with ascites (a condition commonly due to liver disease)

Albusol 4 % also serves to transport certain substances in the body including hormones, enzymes, medicines and also toxins.

2. What you need to know before you are given Albusol 4 %

Albusol 4 % should not be administered to you:

- If you are hypersensitive (allergic) to human albumin or any of the other ingredients of Albusol 4 % (listed in section 6).

Warnings and precautions

Special care should be taken with Albusol 4 %:

If you have a condition where increased blood volume or dilution of the blood could be a problem. Examples of these conditions include heart problems (where the heart is not pumping properly), high blood pressure, blood problems, fluid in the lungs, kidney problems or swollen veins in the oesophagus. Tell your doctor if you have any of these conditions.

- When large quantities of fluid are needed, the amount of important substances normally found in blood may become low. In this case other types of fluid, such as plasma, red blood cells or electrolytes (solutions containing normal body salts/minerals), may also be needed.
- If you get an allergic or shock reaction, the medicine will be stopped immediately and your doctor will have medication available to treat you for shock.

- When there are signs for increased blood volume (headache, breathing disorder, jugular vein congestion) or increased blood pressure. The infusion should be stopped immediately.
- In the USA, a serious condition has been linked to the ingestion of L-tryptophan (which is used as a stabiliser in Albusol 4 %). Symptoms of this condition include rashes, severe muscle and joint pain, difficulty breathing and elevated eosinophil (a type of white blood cell) count.

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,
- 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 as with Albusol 4 %. It is strongly recommended that every time you receive a dose of Albusol 4 % the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Please speak to your doctor should you require additional information in this regard.

Other medicines and Albusol 4 %:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines). Albusol 4 % must not be mixed with other medicines, whole blood and packed red cells.

Albusol 4 % with food and drink:

Albusol 4 % is infused directly into the vein and is not affected by food or drink.

Pregnancy, breastfeeding and fertility:

Pregnancy and breastfeeding

The safety of using Albusol 4 % during pregnancy is not known. However, from clinical experience there have been no harmful effects on the course of pregnancy, the foetus and the newborn.
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Fertility

There is no fertility data available.

Driving and using machines:

It is not always possible to predict to what extent Albusol 4 % may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Albusol 4 % affects them.

Albusol 4 % contains sodium

Sodium is the main component of cooking/table salt.

This medicine contains:

- 0,74 g sodium per 200 ml albumin solution and;
- 1,48 g sodium per 400 ml albumin solution.

This is equal to 37 % and 74 % respectively of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive Albusol 4 %

- Do not share medicines prescribed for you with any other person.
- Your doctor will tell you how long your treatment with Albusol 4 % will last.
- The amount of medicine needed will depend on the reason the medicine is being given and on how well you respond to the treatment. The dose will be calculated by your doctor. Your doctor will regularly monitor how the medicine is affecting you by checking your blood pressure, pulse, volume of urine passed and the quantity of iron and salt in your blood.
- In children, the amount given will depend on the weight of the child. Your doctor will calculate the dose.
- Your doctor may want to record the batch number of your medicine in your file.

You will not be expected to give yourself Albusol 4 %. It will be given to you by a person who is qualified to do so. The medicine will be given as an intravenous infusion (an injection given very slowly into a vein). It does not need to be given through a filter. The rate will depend on how your body responds to the medication and the condition for which it is being used.

If you receive more Albusol 4 % than you should:

Your condition will be checked regularly while you are on this medicine. Signs of too much fluid being given are headache, high blood pressure, difficulty in breathing while lying down and high pressure in your heart, which your doctor will measure.

Since a health care provider will administer Albusol 4 %, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Albusol 4 %:

Since a health care provider will administer Albusol 4 %, it is unlikely that a dose will be missed.

4. Possible side effects

Albusol 4 % can have side effects.

Not all side effects reported for Albusol 4 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

If any of the following happens, stop using Albusol 4 % and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing;
- skin rash;
- fall in blood pressure;
- difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Albusol 4 %. You may need urgent medical attention or hospitalisation. In very rare cases, the sudden high fluid volume resulting from treatment with Albusol 4 % could cause a fluid overload, dilution of the blood and accumulation of fluid in the lung (leading to difficulty in breathing). You should advise your doctor if you have heart problems.

Tell your doctor if you notice any of the following:

- nausea, vomiting, increased salivation;
- shivers;
- feeling feverish;
- flushing.

These do not happen very often and are usually mild.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (https://primaryreporting.who-umc.org/ZA) found on SAHPRA website or to National Bioproducts Institute NPC via the email address Pharmacovigilance@nbisa.org.za. By reporting side effects, you can help provide more information on the safety of Albusol 4 %.

5. How to store Albusol 4 %

Store all medicines out of reach of children.

Store at or below 25 ˚C.

Do not freeze.

Store upright.

Keep the bottle in the outer carton until required for use.

Protect from light.

Each bottle is intended to be used once only. Due to the absence of any antimicrobial preservative, it is recommended that Albusol 4 % should be used immediately after opening. If the liquid is cloudy or has small particles in it, it should not be used. Do not use Albusol 4 % after the expiry date stated on the label. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Albusol 4 % contains

- The active substance is a sterile solution of 0,04 g/ml human albumin (a protein that occurs naturally in your body and is needed for many different functions).
- The other ingredients are sodium chloride, N-Acetyltryptophan, caprylic acid, hydrochloric acid, sodium hydroxide and water for injections.

Albusol 4 % does not contain any preservatives. The pH of the solution is neutral (pH 7).

What Albusol 4 % looks like and contents of the pack

Albusol 4 % is presented as a solution for infusion.

The solution is a clear, slightly viscous liquid which is almost colourless to amber in colour.

The following pack sizes are available:

- **200 ml:** Albusol 4 % solution is packed in a clear glass bottle, closed with a rubber closure and an aluminium tear-off cap.
- **400 ml:** Albusol 4 % solution is packed in a clear glass bottle, closed with a rubber closure and an aluminium tear-off cap.
- **Each** 200 ml bottle contains 8 g of human albumin and each 400 ml bottle contains 16 g of human albumin.

Each pack size consists of a bottle of Albusol 4 % and an airvent set. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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