1.3.2 Proposed Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Albusol 20 %, human plasma albumin 20 %, solution for IV Infusion

Read all of this leaflet carefully before you are given Albusol 20 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Albusol 20 %** 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.

1. WHAT ALBUSOL 20 % CONTAINS

- The active substance is a sterile solution of human plasma albumin (a protein that occurs naturally in your body and is needed for many different functions). It is made from human plasma of healthy, volunteer, unpaid donors in South Africa. **Albusol 20 %** is available in 2 different pack sizes: 50 ml and 100 ml. The 50 ml bottle contains 10 g of human albumin and the 100 ml bottle contains 20 g of human albumin.

  The other ingredients are citrate, potassium and sodium ions in small quantities as well as sodium acetyltryptophanate and sodium caprylate, which stabilizes the

Albusol 20 %.

Albusol 20 % does not contain any preservatives. The pH of the solution is neutral (pH 7).

2. WHAT ALBUSOL 20 % IS USED FOR

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 20 %** has four times the amount of albumin as plasma.

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 affects their absorption, production and breakdown
- Removal of fluid from the abdomen in patients with ascites (a condition commonly due to a liver problem)
- Patients undergoing dialysis (artificial cleansing of the blood)

Albusol 20 % also serves to transport certain substances in the body including hormones, enzymes, medicines and also toxins.

3. BEFORE ALBUSOL 20 % IS ADMINISTERED

Do not administer Albusol 20 %:

- if you are hypersensitive to human plasma albumin or any of the other ingredients of **Albusol 20 %**.
- 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 chronic liver disease. Tell your doctor if you have any of these conditions.
- **Albusol 20 %** should not be given to dehydrated patients unless other salt solutions are also given.

Tell your doctor or healthcare professional before being given the injection:

- 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.
- Your doctor will also need to ensure that you have sufficient fluid circulating in your body. He will monitor you to make sure that the volume of fluid is not too high such that your heart cannot pump properly.
- If large quantities of **Albusol 20 %** are required, you may also need to be given other fluids such as salts to maintain a normal fluid balance. Alternatively, your doctor may continue your treatment with albumin 4 %**.**

- If you get an allergic or shock reaction, your medicine will be stopped immediately and your doctor will have medication available to treat you for shock.
- In the USA, a serious condition has been linked to the ingestion of L-tryptophan (which is used as a stabiliser in **Albusol 20 %**). Symptoms of this condition include rashes, severe muscle and joint pain, difficulty breathing and elevated eosinophil (a type of white blood cell) count. Please speak to your doctor if you require more information about this condition.

Receiving Albusol 20 % with food and drink:

Albusol 20 % is infused directly into the vein and is not affected by food or drink.

Pregnancy and breastfeeding:

The safety of using **Albusol 20 %** during pregnancy is not known. However, albumin is a normal component of blood and may therefore be used if required.

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:

Make sure you know how this medicine affects you before you drive or operate machines.

Important information about some of the ingredients of Albusol 20 %:

Albusol 20 % is prepared from human plasma. When medicinal products prepared from human plasma are given to patients, it is possible that some infectious diseases could be passed on, including some which may not yet have been discovered. To reduce the risk from such viruses, strict measures are applied to the selection and testing of blood donors and donations. Each unit of plasma is tested for antibodies to human immunodeficiency virus (HIV), hepatitis C virus and hepatitis B surface antigen using approved methods. Only plasma in which none of these viruses are found is processed further. In addition, the pooled plasma is also tested for the presence of these viruses and only processed further if the virus is not found. The manufacturing process also involves steps which are aimed at removing virus including a process of pasteurisation. Please speak to your doctor should you require additional information in this regard.

Using other medicines with Albusol 20 %:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

However, other medicines are unlikely to affect your treatment with

Albusol 20 %.

4. HOW TO RECEIVE ALBUSOL 20 %

- Do not share medicines prescribed for you with any other person.
- Your doctor will tell you how long your treatment with **Albusol 20 %** 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. You may also need to have a blood transfusion to replace the iron content of your blood to prevent anaemia.
- 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.

How will **Albusol 20 %** be given:

You will not be expected to give yourself **Albusol 20 %.** It will be given to you by a person who is qualified to do so.

The medicine will be given as an 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.

Albusol 20 % must not be diluted with water as this could cause a breakdown of your red blood cells. If a diluted solution of **Albusol 20 %** is required, human albumin 4 % solution should be used.

If you use more Albusol 20 % 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. In the unlikely event that too much medicine is given, the infusion will be stopped immediately and the doctor may give you treatment to remove the excess fluid.

If you missed a dose of Albusol 20 %:

This does not apply to you as **Albusol 20 %** will only be administered by your doctor or other health care professional when you require it.

Effects when treatment with Albusol 20 % is stopped:

It is unlikely that you will experience any negative effects when you stop taking this product.

5. POSSIBLE SIDE EFFECTS

Albusol 20 % can have side effects. These do not happen very often and are usually mild. Some patients may feel nauseous, shiver, feel feverish or have flushes. Some patients may get an allergic reaction to the medicine, ranging from a mild skin rash to more serious cases of shock (when your blood pressure falls dangerously low). Your doctor will stop the medicine and treat the reaction if it occurs.

In very rare cases the sudden high fluid volume resulting from treatment with **Albusol 20 %** 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.

Not all side effects reported for **Albusol 20 %** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking 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.

6. STORING AND DISPOSING OF ALBUSOL 20 %

Store all medicines out of reach of children.

Store in a cool dry place at or below 25 °C. It should be kept out of light until required

Each bottle is intended to be used once only. Due to the absence of any antimicrobial preservative it is recommended that once the medicine's stopper has been pierced, your medicine should start to be used immediately and in any case should be used within 3 hours. If the liquid is cloudy or has small particles in it, it should not be used.

Do not use **Albusol 20 %** 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)

7. PRESENTATION OF ALBUSOL 20 %

Albusol 20 % is packed in a clear glass bottle, closed with a rubber **[**~~bung~~**]** stopper and a sealed cap. The bottle is filled with either 50 ml or 100 ml of solution.

8. IDENTIFICATION OF ALBUSOL 20 %

Albusol 20 % is a clear yellowish-orange solution.

9. REGISTRATION NUMBER

T/30.3/739

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NATIONAL BIOPRODUCTS INSTITUTE

PRIVATE BAG X9043

PINETOWN

3600

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11. DATE OF PUBLICATION

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