

PROFESSIONAL INFORMATION

SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT
blood bag

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)
solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE

ANTICOAGULANT contains:

| | Quantity per 63 ml |
|---------------------------------|--------------------|
| Citric acid monohydrate | 0,206 g |
| Sodium citrate dihydrate | 1,6569 g |
| Sodium acid phosphate dihydrate | 0,1581 g |
| Dextrose (Glucose monohydrate) | 1,6065 g |

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE

MANNITOL (SAG-M) contains:

| | Quantity per 100 ml |
|--------------------------------|---------------------|
| Dextrose (Glucose monohydrate) | 0,900 g |
| Sodium chloride | 0,877 g |
| Adenine | 0,0169 g |
| Mannitol | 0,525 g |

Approximate electrolyte concentration: Sodium 150 mEq/L
Chloride 150 mEq/L

For full list of excipients, see section 6.1.

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3. PHARMACEUTICAL FORM

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

A clear, colourless or faintly straw coloured solution free from deposit.

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M):

A colourless or faintly straw coloured, transparent liquid, free from deposit.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT solution is indicated as a blood preservative in instances where storage of collected blood is required for periods up to 28 days.

The dilution effect that **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** has on the concentrated red cells is important for rapid administration of red blood cells during medical emergencies and in surgical procedures.

4.2 Posology and method of administration

Posology

Blood is collected into a triple blood pack unit, **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** containing 63 ml of solution, for the collection of 450 ml of blood. Attached to the primary pack is an **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** containing 100 ml of solution and an empty secondary transfer pack for plasma separation.

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Method of administration

A. *General instructions for use*

1. Use aseptic technique.
2. Apply a blood pressure cuff or place a tourniquet.
3. Disinfect site of venepuncture.
4. Tie tourniquet or inflate pressure cuff to 60 mm Hg.
5. Clamp donor tube, remove needle cover and perform venepuncture.
6. Release clamp from donor tube to permit flow of blood.
7. Mix blood and anticoagulant at several intervals during collection and immediately after collection.
8. Collect the quantity of blood within the limits indicated on the pack label.
9. Collect pilot samples using the sampling pouch and the appropriate sampling tubes and clamps, as described below.
10. Remove tourniquet or release pressure in cuff and withdraw needle.

B. *Blood collection*

1. Close the white clamp to the primary collection pack.
2. To remove the needle cap, twist to break the tamper-proof seal between the needle and its cap and remove it by sliding it down the axis of the needle. Perform the venepuncture.
3. Break the cannula next to the sampling pouch by bending the rigid part back and forth 3 times at 90 °. Allow the sampling pouch to fill to the desired level.
4. Close the blue clamp to the sampling pouch and immediately open the white clamp to the primary collection pack.
5. The closed blue clamp, a permanent closure device, will ensure the sampling line is sealed.
6. Proceed then immediately to blood sampling by opening the holder (if a cap is present), then by collecting samples in vacuum tubes with stopper oriented upwards.

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7. Ensure regular agitation during the course of collection, in order to allow mixing of blood with the anticoagulant solution.
8. Collect the quantity of blood within the limits indicated on the pack label.
9. When the collection is completed, seal the donation tube by closing the white clamp.
10. Loosen the tourniquet or deflate the pressure cuff.
11. If necessary, strip the donor tubing towards the collection pack, mix and leave the tubing filled with new blood.
12. Store the whole blood unit according to appropriate regulations.

c. Instructions for blood component preparation

1. Follow the stated instructions for blood collection and sampling (see **A. General instructions for use** and **B. Blood collection**).
2. The blood component preparation should be performed within 24 hours after blood collection.
3. Blood component preparation for the triple blood pack to be performed as required by the blood transfusion service.

4.3 Contraindications

None

4.4 Special warnings and precautions for use

This solution is not intended for administration in its original form.

4.5 Interaction with other medicines and other forms of interaction

None

4.6 Fertility, pregnancy, and lactation

Safety in pregnancy and lactation has not been established.

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4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

a. Summary of the safety profile

The safety of infusions of more than 5 units of **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** has not been established.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

For reporting of side effects directly to the holder of the certificate of registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

4.9 Overdose

None

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.8.2 (Anticoagulants)

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT is a preservative used in the storage of human blood. The preservative ability of the solution is determined by the various components and the amount of each component in the solution. The inclusion of glucose in the solution prevents haemolysis of the red blood corpuscles of the stored blood and supports cell metabolism, while the inorganic phosphate present helps to maintain the adenosine triphosphate (ATP) levels necessary to ensure viability of the erythrocytes and buffers the solution.

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In current transfusion practice, platelet concentrate and/or plasma are frequently manufactured from donor blood shortly after collection. Depending on the type of product prepared, the red blood cells may be concentrated during centrifugation to haematocrits varying between 70 % and 90 %.

Sufficient metabolic substrate is present in the volume of preservative solution/plasma in the lower haematocrit and this provides satisfactory post transfusion 24-hour red cell survival following cell storage. However, there is a trend toward decreased post transfusion red cell survival as the haematocrit increases above 80 %.

In addition, packed erythrocytes with high haematocrits have a high viscosity and often must be mixed with saline or other suitable fluid to increase flow rates prior to clinical infusion.

Adenine preserves the viability of stored red blood cells. Along with adenine, other ingredients in **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** are glucose, which serves as a metabolic substrate for the cells during storage, and mannitol, which has been shown to be beneficial in reducing haemolysis during the storage.

5.2 Pharmacokinetic properties

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

Sodium hydroxide (pH adjuster) and water for injections

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG- M):

Hydrochloric acid (pH adjuster) and water for injections

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6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C. It is recommended that units removed from the tri-laminated pouches are not kept for longer than 7 days. Store blood between 2 °C and 6 °C.

6.5 Nature and contents of container Triple blood pack units:

One 63 ml **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** (Reg. No.: D/8.2/263), one 100 ml **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** (Reg. No.: 35/8.2/0025) and one empty transfer pack/empty PL732 platelet storage pack. The triple blood pack unit is packed into a tri-laminated pouch.

6.6 Special precautions for disposal and other handling

Not applicable

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg 2013

Tel: +27 11 494 8000

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8. REGISTRATION NUMBER(S)

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

D/8.2/263

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG- M):

35/8.2/0025

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

14 June 1972

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG- M):

15 November 2002

10. DATE OF REVISION OF THE TEXT

11 November 2024

PI 11 November 2024