

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0****ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** blood bag

Citric acid monohydrate, sodium citrate dihydrate, sodium acid phosphate dihydrate, dextrose (glucose monohydrate)

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

Dextrose (glucose monohydrate), sodium chloride, adenine, mannitol

Read all of this leaflet carefully because it contains important information for you.

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** is available without a doctor's prescription. Nevertheless, you still

need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-BLOOD PRIMARY AND SECONDARY CONTAINERS with any other person.

Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** is and what it is used for
2. What you need to know before you use **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)**

3. How to use **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)**
4. Possible side effects
5. How to store **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)**
6. Contents of the pack and other information

1. What ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) is and what it is used for

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) is available as a triple blood pack unit which is used for the collection and preservation of blood.

2. What you need to know before you use ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)**.

Safety in pregnancy and lactation has not been established.

3. How to use ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)

Blood is collected into the triple blood pack unit.

You will not be expected to use **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** by yourself. Your blood will be taken by a person who is qualified to do so.

Since a healthcare provider will take your blood, he/she will control the amount of blood taken.

4. Possible side effects

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** can have side effects.

Not all side effects reported for **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** and **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)**, please consult your healthcare provider for advice.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care 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.

5. How to store ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)

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. Contents of the pack and other information

What ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) contains

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

The active substances are citric acid monohydrate, sodium citrate dihydrate, sodium acid phosphate dihydrate and dextrose (glucose monohydrate).

The other ingredients are sodium hydroxide (pH adjuster) and water for injections.

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

The active substances are dextrose (glucose monohydrate), sodium chloride, adenine and mannitol.

The other ingredients are hydrochloric acid (pH adjuster) and water for injections.

What ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT and ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) looks like and contents of the pack

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.

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.

Holder of Certificate of Registration

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This leaflet was last revised in

11 November 2024

Registration number

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

PIL 11 November 2024

PASIËNT INLIGTINGSVOUBILJET

SKEDULERINGSSTATUS: S0

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT bloedsak
Sitreensuurmonohidraat, natriumsitraatdihidraat, natriumsuurfosfaatdihidraat, dekstrose (glukosemonohidraat)

ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) oplossing
Dekstrose (glukosemonohidraat), natriumchloried, adenien, mannitol

Lees hierdie hele voubiljet noukeurig deur, want dit bevat belangrike inligting vir u.

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en
ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) is
beskikbaar sonder 'n doktersvoorskrif. Nietemin moet u dit steeds versigtig gebruik om die beste resultate daaruit
te verkry.

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Moenie ADCO-BLOOD PRIMARY EN SECONDARY CONTAINERS met enige ander persoon deel nie.

Raadpleeg u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat in hierdie voubiljet is

1. Wat **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** gebruik
3. Hoe om **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** te gebruik
4. Moontlike newe-effekte
5. Hoe om **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) is en waarvoor dit gebruik word

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) is beskikbaar as 'n drievoudige bloedpak-eenheid wat gebruik word vir die versameling en bewaring van bloed.

2. Wat u moet weet voordat u ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) gebruik

Hierdie oplossing is nie bedoel vir toediening in sy oorspronklike vorm nie.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** gebruik.

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

3. Hoe om ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) te gebruik

Bloed word in die drievoudige bloedpak-eenheid versamel.

Daar sal nie van u verwag word om **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** op u eie te gebruik nie. U bloed sal onttrek word deur 'n persoon wat bekwaam is om dit te doen.



ADCO-BLOOD

Aangesien 'n gesondheidsorgverskaffer u bloed sal onttrek, sal hy/sy die hoeveelheid bloed wat onttrek word, beheer.

4. Moontlike newe-effekte

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** kan newe-effekte hê.

Nie alle newe-effekte wat aangemeld is vir **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste effekte ervaar terwyl u **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte

Dit is belangrik om vermoedelike nadelige reaksies na goedkeuring van die medisyne aan te meld. Dit laat voortgesette monitering van die voordeel/risiko-balans van die medisyne toe. Gesondheidsorgverskaffers word versoek om enige vermoedelike nadelige geneesmiddelreaksies by SAHPRA aan te meld via die Med Safety Toep (Medsafety X SAHPRA) en elektroniese aanmeldingsplatform (who-umc.org) wat op die SAHPRA se webwerf gevind word.

5. Hoe om **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** en **ADCO- BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** te bêre

Bêre teen of benede 25 °C. Dit word aanbeveel dat eenhede wat uit die drieledig-gelamineerde sakke verwyder is, nie langer as 7 dae gehou word nie. Bêre bloed tussen 2 °C en 6 °C.

ADCO-BLOOD

6. Inhoud van die verpakking en ander inligting

Wat ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) bevat

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

Die aktiewe bestanddele is sitroensuurmonohidraat, natriumsitraatdihidraat, natriumsuurfosfaatdihidraat en dekstrose (glukosemonohidraat).

Die ander bestanddele is natriumhidroksied (pH-aanpasser) en water vir inspuittings.

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

Die aktiewe bestanddele is dekstrose (glukosemonohidraat), natriumchloried, adenien en mannitol.

Die ander bestanddele is soutsuur (pH-aanpasser) en water vir inspuittings.

Hoe ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT en ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M) lyk en die inhoud van die verpakking

ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT:

'n Helder, kleurlose of effens strooikleurige oplossing vry van neerslag.

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

'n Kleurlose of effens strooikleurige, deursigtige vloeistof, vry van neerslag.

Drievoudige bloedpak-eenhede:

Een 63 ml **ADCO-BLOOD PRIMARY CONTAINER WITH CITRATE PHOSPHATE GLUCOSE ANTICOAGULANT** (Reg. Nr.: D/8.2/263), een 100 ml **ADCO-BLOOD SECONDARY CONTAINER WITH SALINE ADENINE GLUCOSE MANNITOL (SAG-M)** (Reg. No.:35/8.2/0025) en een leë oordragpak/leë PL732-bloedplaatjie-opbergpak. Die drievoudige bloedpak-eenheid word in 'n drie-ledig gelamineerde sakkie verpak.

ADCO-BLOOD

Houer van Registrasiesertifikaat

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Hierdie voubiljet mees onlangs hersien op

11 November 2024

Registrasienuommer

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

PIL 11 November 2024