

CARDIOPLEGIC SOLUTION A ADCO
 CARDIOPLEGIC SOLUTION B ADCO
 CARDIOPLEGIC SOLUTION C ADCO

Adcock Ingram Critical Care (Pty) Ltd.
 30 January 2018

Sterile solution for maintaining cardioplegic

1.3.1.1 COMBINED PROFESIONAL INFORMATION

SCHEDULING STATUS: S3

PROPRIETARY NAME (and dosage form)

CARDIOPLEGIC SOLUTION A ADCO

CARDIOPLEGIC SOLUTION B ADCO

CARDIOPLEGIC SOLUTION C ADCO

(STERILE SOLUTION FOR MAINTAINING CARDIOPLEGIC)

COMPOSITION:

	CARDIOPLEGIC SOLUTION A ADCO gram per 950 ml	CARDIOPLEGIC SOLUTION B ADCO gram per 50 ml	CARDIOPLEGIC SOLUTION C ADCO gram per 950 ml
Sodium Chloride	5,99	-	5,99
Potassium Chloride	1,80	-	0,89
Maqnesium Chloride (Hexahydrate)	0,299	-	0,299
Sodium Bircarbonate	3,22	-	3,22
Mannitol	12,47	-	12,47
Calcium Chloride (Dihydrate)	-	0,132	-
Glucose (Monohydrate)	-	10,2	-

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(After mixing, the electrolyte concentrations will be as follows:

950 ml CARDIOPLEGIC SOLUTION A ADCO mixed with 50 ml CARDIOPLEGIC SOLUTION B ADCO		950 ml CARDIOPLEGIC SOLUTION C ADCO mixed with 50 ml CARDIOPLEGIC SOLUTION B ADCO	
APPROXIMATE MILLIMOLES PER LITRE			
Sodium	140,7	Sodium	140,7
Potassium	24,1	Potassium	12,0
Magnesium	1,5	Magnesium	1,5
Calcium	0,9	Calcium	0,9
Bicarbonate	38,3	Bicarbonate	38,3
Chloride	131,3	Chloride	119,3
Mannitol	68,4	Mannitol	68,4
Glucose	50,5	Glucose	50,5
Approximate pH	7,60	Approximate pH	7,60
Approximate milliosmoles per litre	456	Approximate milliosmoles per litre	432

CARDIOPLEGIC SOLUTION B ADCO must be aseptically mixed with **CARDIOPLEGIC SOLUTION A ADCO** or **CARDIOPLEGIC SOLUTION C ADCO** by means of a sterile transfer set with two stopper needles (AFC 0423).

PHARMACOLOGICAL CLASSIFICATION:

A.24 (Mineral substitutes, electrolytes)

PHARMACOLOGICAL ACTION:

The electrolyte composition of the formulation induces cardiac arrest by depolarization of the cardiac muscle. Energy demands are lowered since electromechanical work is avoided under induced ischaemia resulting from aortic clamping. Myocardial hypothermia reduces metabolism and the presence of a small amount of glucose serves as a substrate for continued energy production. Production of immediate arrest reduces myocardial energy requirements to that the small energy output of anaerobic metabolism can be channelled towards maintenance of cell membrane integrity rather than being wasted on electromechanical work (beating or fibrillating).

Factors enhancing safe aortic clamping include:

- a) hypothermia which lowers energy demands and delays the build-up of acid metabolites which inhibits anaerobiosis;
- b) substrate enhancement;
- c) buffering which counteracts lactic acidosis and hyperosmolarity which reduces the oedema resulting from ischaemia and hypothermia.

INDICATIONS:

Myocardial protection during extracorporeal circulation in cardiac bypass surgery.

CONTRA-INDICATIONS:

No known contra-indications.

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WARNINGS and SPECIAL PRECAUTIONS:

Solutions containing sodium should be used with great care in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists oedema with or without sodium retention.

Solutions containing potassium ions should be used with great care in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

Solutions containing calcium ions should not be administered through the same administration set as blood anticoagulated with calcium chelators, e.g. Anticoagulant Citrate Glucose or Citrate Phosphate Glucose because of the likelihood of coagulation.

The intravascular administration of these solution can cause fluid and/or solute overloading, resulting in dilution of serum concentrations, overhydration, congested states or pulmonary oedema.

Additives may be incompatible. Consult with pharmacist if necessary, to ensure compatibility of prescribed additives. When introducing additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Do not administer unless the solution is clear and the seal is intact.

The solution should be kept refrigerated after admixing and used within 24 hours.

INTERACTIONS:

Interaction studies have not been performed or no interactions have been experienced.

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PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Initial infusion of one litre of **CARDIOPLEGIC SOLUTION A ADCO** and **CARDIOPLEGIC SOLUTION B ADCO** in 300 ml increments is used in order to effect cardioplegia immediately following aortic clamping. The solution is infused under positive pressure using a positive displacement pump. Maintenance of cardioplegic is effected by the administration of **CARDIOPLEGIC SOLUTION B ADCO** and **CARDIOPLEGIC SOLUTION C ADCO** or **CARDIOPLEGIC SOLUTION A ADCO** and **CARDIOPLEGIC SOLUTION B ADCO** and maintained for the duration of the procedure.

SIDE-EFFECTS:

Reactions which may occur because of the solution or the technique of administration include febrile response, extravasation and hypervolemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms of overdosage and particulars of its treatment has not been established.

IDENTIFICATION:

A clear, colourless solution.

PRESENTATION:

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CARDIOPLEGIC SOLUTION A ADCO and **CARDIOPLEGIC SOLUTION C ADCO** are available in one litre glass bottles containing 950 ml solution.

CARDIOPLEGIC SOLUTION B ADCO is available in a 250 ml glass bottle containing 50 ml solution.

STORAGE INSTRUCTIONS:

Store below 25 °C.

After mixing, the solution should be refrigerated (2 °C - 4 °C) and the unused portion discarded after 24 hours.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

CARDIOPLEGIC SOLUTION A ADCO: SX/24/266

NA: NS2 90/34/00198

BW: S2 B9310190

CARDIOPLEGIC SOLUTION B ADCO: SX/24/267

NA: NS2 90/34/00199

BW: S2 B9309760

CARDIOPLEGIC SOLUTION C ADCO: SX/24/268

NA: NS2 90/34/00200

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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