Name of the Medicine

Plasma-Lyte 56 and 5% Glucose IV Infusion (Multiple Electrolyte and Glucose Injection).

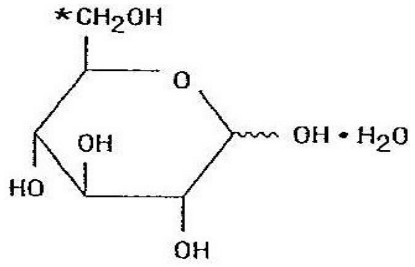
Description

Plasma-Lyte 56 and 5% Glucose IV Infusion is a sterile, clear, non-pyrogenic hypertonic solution in a single dose container for intravenous administration.

Each 1000 mL of Plasma-Lyte 56 and 5% Glucose IV Infusion contains:

Sodium Chloride	2.34g
Potassium acetate	1.28g
Magnesium Acetate	320mg
Glucose-anhydrous	50g
Hydrochloric acid	pH adjustment
Water for Injections	q.s. to 1000 mL
pH range	3.5 to 6.0.
Approximate Osmolality	401 mOsm/kg
Approximate Kilojoules	835 kJ

Plasma-Lyte 56 and 5% Glucose IV Infusion when administered intravenously, is a source of water, electrolytes, and calories. It contains no antimicrobial agents. The approximate osmolality is 401mOsm/kg. An injection with an osmolality within the range of 250 to 350 mOsm/kg is considered to be isotonic. Plasma-Lyte 56 and 5% Glucose IV Infusion is a hypertonic solution. Administration of substantially hypertonic solutions may cause vein damage.



α-Glucopyranose monohydrate

Each 1000 mL of Plasma-Lyte 56 and 5% Glucose IV Infusion has an ionic concentration of:

Sodium	40 mmol
Potassium	13 mmol
Magnesium	1.5 mmol
Chloride	40 mmol
Acetate	16 mmol
Glucose	278 mmol

Pharmacology

Plasma-Lyte 56 and 5% Glucose IV Infusion is a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Plasma-Lyte 56 and 5% Glucose IV Infusion produces a metabolic alkalinising effect. Acetate ions are metabolised ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications

Plasma-Lyte 56 and 5% Glucose IV Infusion is indicated as a source of water, electrolytes and calories or as an alkalinising agent.

Contraindications

Solutions containing glucose may be contraindicated in patients with known allergy to corn or corn products.

Plasma-Lyte 56 and 5% Glucose IV infusion is contraindicated in patients with a known hypersensitivity to the product.

Plasma-Lyte 56 and 5% Glucose IV infusion must not be used in patients with clinically significant hyperglycemia

Precautions

Plasma-Lyte 56 and 5% Glucose IV Infusion should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo-agglutination or haemolysis.

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with Plasma-Lyte 56 and 5% Glucose IV Infusion. The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Plasma-Lyte 56 and 5% Glucose IV Infusion is a hyper-osmotic solution, having an osmolality of 401mOsm/kg. Administration of hypertonic solutions may cause venous irritation including phlebitis. Hyperosmolar solution should be administered with caution, if at all, to patients with hyperosmolar states eg. hypochloraemic hypokalaemic alkalosis due to prolonged vomiting, pyloric stenosis, prolonged nasogastric suctioning.

Plasma-Lyte 56 and 5% Glucose IV Infusion is not indicated for
- the treatment of hypochloraemic hypokalaemic alkalosis.
- the primary treatment of severe metabolic acidosis.
- hypomagnesaemia

Although Plasma-Lyte 56 and 5% Glucose IV Infusion has a potassium concentration similar to the concentration in plasma, it is insufficient to product a useful effect in case of severe potassium deficiency; therefore, it should not be used for correction of severe potassium deficiency.

Plasma-Lyte 56 and 5% Glucose IV Infusion is not for use in patients with hyperkalaemia. It should be used with caution, if at all, in patients with conditions predisposing to hyperkalaemia (such as severe renal impairment or adrenocortical insufficiency, acute dehydration or extensive tissue injury or burns) and in patients with cardiac disease, and in conditions where potassium retention is present.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate ions should be done with great care in those conditions in which there is an increased level or an impaired utilisation of these ions, such as severe hepatic insufficiency.

Depending on the volume and rate of infusion, intravenous administration of Plasma-Lyte 56 and 5% Glucose IV Infusion can cause:

- Fluid and/or solute overload resulting in overhydration/hypervolaemia and, for example, congested states including pulmonary congestion and oedema.
- Clinically relevant electrolyte disturbances and acid-base imbalance.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of the infusion. The risk of solute overload causing congested states with peripheral and pulmonary oedema is directly proportional to the electrolyte concentrations of the infusion.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be administered with particular caution, to hypervolaemic or overhydrated patients.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists oedema with sodium retention, fluid overload and oedema, such as patients with primary hyperaldosteronism, secondary hyperaldosteronism (associated with, for example, hypertension, congestive heart failure, renal artery stenosis or nephrosclerosis) or preeclampsia.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be used with particular caution, if at all, in patients with alkalosis, or at risk for alkalosis. Excess administration may result in metabolic alkalosis.

Solutions containing magnesium should be used with caution, if at all, in patients with:

- Hypermagnesaemia or conditions predisposing to hypermagnesaemia including, but not limited to severe renal impairment or magnesium therapy such as eclampsia.
- Myasthenia gravis

In patients with diminished renal function, administration of Plasma-Lyte 56 and 5% Glucose IV Infusion may result in sodium and/or potassium or magnesium retention.

Plasma-Lyte 56 and 5% Glucose IV Infusion contains no calcium and an increase in plasma pH due to its alkalinising effect may lower the concentration of ionised (not protein-bound) calcium.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be administered with particular caution, if at all, to patients with hypocalcaemia.

Plasma-Lyte 56 and 5% Glucose IV Infusion should be used with caution in patients with impaired glucose tolerance or diabetes mellitus.
In order to avoid hyperglycaemia, the infusion rate should not exceed the patient's ability to utilise glucose. Hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes. Caution is recommended in using glucose-containing solutions in such patients.

Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury. Glucose-containing solutions should, therefore, be used with caution in patients with head injury, in particular during the first 24 hours following the trauma.

If hyperglycaemia occurs, the rate of glucose administration should be reduced and/or insulin administered, or the insulin dose adjusted.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Pressurising intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

Use in Pregnancy (No Category)
Intrapartum maternal intravenous infusion of glucose-containing solutions may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate. Physicians should carefully consider the potential risks and benefits for each specific patient before administering Plasma-Lyte 56 and 5% Glucose IV Infusion.

Use in Lactation
There are no adequate data from the use of Plasma-Lyte 56 and 5% Glucose IV Infusion in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using Plasma-Lyte 56 and 5% Glucose IV Infusion in lactating women.

Paediatric Use
Safety and effectiveness of Plasma-Lyte 56 and 5% Glucose IV Infusion in paediatric patients have not been established by adequate or well controlled trials, however, the use of electrolyte solutions in the paediatric population is referenced in the medical literature. The precautions and adverse reactions identified in this document should be observed in the paediatric population.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in paediatric intravenous fluid therapy.

In very low birth weight infants, excessive or rapid administration of glucose injection may result in increased serum osmolarity and possible haemorrhage.

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycaemic control in order to avoid potential long term adverse effects. Hypoglycaemia in the newborn can cause prolonged seizures, coma and brain damage. Hyperglycaemia has been associated with intraventricular haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotising enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death. Therefore, acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Use in the Elderly
Clinical studies of Plasma-Lyte 56 and 5% Glucose IV Infusion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or medicine therapy.

When selecting the type of infusion solution and the volume/rate of infusion for an elderly patient, consider that elderly patients are generally more likely to have cardiac, renal, hepatic and other diseases or concomitant drug therapy.

Carcinogenicity
Studies with Plasma-Lyte 56 and 5% Glucose IV Infusion have not been performed to evaluate carcinogenic potential.

Genotoxicity
Studies with Plasma-Lyte 56 and 5% Glucose IV Infusion have not been performed to evaluate mutagenic potential.

Effects on fertility
Studies with Plasma-Lyte 56 and 5% Glucose IV Infusion have not been performed to evaluate effect on fertility.

Effect on laboratory tests
There have been reports of false-positive test results using the Bio Rad Laboratories Platelia *Aspergillus* EIA test in patients receiving Baxter gluconate containing Plasma-Lyte solutions. These patients were subsequently found to be free of *Aspergillus* infection. Therefore, positive test results for this test in patients receiving Baxter gluconate containing Plasma-Lyte solutions should be interpreted cautiously by other diagnostic methods.

Interactions with other Medicines

Caution must be exercised in the administration of Plasma-Lyte 56 and 5% Glucose IV Infusion to patients treated with drugs that may increase the risk of sodium and fluid retention such as corticosteroids or corticotropin.
Caution is advised when administering Plasma-Lyte 56 and 5% Glucose IV Infusion to patients treated with drugs for which renal elimination is pH dependent. Due to its alkalinising effect (formation of bicarbonate), Plasma-Lyte 56 and 5% Glucose IV Infusion may interfere with the elimination of such drugs:

- renal clearance of acidic drugs such as salicylates, barbiturates and lithium may be increased
- renal clearance of alkaline drugs such as sympathomimetics (eg. ephedrine, pseudoephedrine, quinidine or dextroamphetamine (dexamphetamine) sulfate may be decreased.

Because of its potassium content, Plasma-Lyte 56 and 5% Glucose IV Infusion should be administered with caution in patients treated with agents or products that can cause hyperkalaemia or increase the risk of hyperkalaemia, such as potassium sparing diuretics (amiloride, spironolactone, triamterene) with ACE inhibitors, angiotensin II receptor antagonists or the immunosuppressants tacrolimus and cyclosporine.

Administration of potassium in patients treated with such medications can produce severe and potentially fatal hyperkalemia, particularly in patients with severe renal insufficiency.

General
The Viaflex plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solution in contact with the plastic container can leach out certain chemical components from the plastic in very small amounts however; biological testing was supportive of the safety of the plastic container material.

Adverse Effects

Reactions that may occur because of the solution or the technique of administration include febrile response or infection at the site of infusion. Other reactions that may occur include:

Circulatory effects: Extravasation
Hypervolaemia
Venous thrombosis
Phlebitis extending from the site of injection

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

The following adverse reactions have been reported in the post-marketing experience with unspecified Plasma-Lyte products and Plasma-Lyte products without Glucose (listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity, where feasible):

IMMUNE SYSTEM DISORDERS:
Hypersensitivity/infusion reactions including anaphylactoid reaction and the following manifestations: hypotension, chest discomfort, dyspnoea, wheezing, flushing, hyperaemia, asthenia, urticaria, cold sweat, pyrexia and chills.

METABOLISM AND NUTRITION DISORDERS:
Hyperkalaemia and hyperglycaemia

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS:
Infusion site reaction (eg. burning sensation)

Other adverse reactions reported with Plasma-Lyte products without glucose are: other manifestations of hypersensitivity/infusion reactions including tachycardia, palpitations, chest pain, respiratory rate increased, feeling abnormal, piloerection, oedema peripheral and infusion site pain.

Dosage and Administration

Dosage

As directed by the physician. Dosage is dependent on age, weight and clinical condition of the patient as well as laboratory determinations. Dosage, rate and duration of administration are to be individualised and depends upon the indication for use, the patient's age, weight, clinical condition and concomitant treatment and on the patient's clinical and laboratory response to treatment.

The infusion rate and volume of intravenous solutions containing glucose should be selected with caution in children.

Each Viaflex container is for single patient use only.

All injections in Viaflex plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage and constant infusion rate of intravenous glucose must be selected with caution in paediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycaemia/hypoglycaemia.

Directions for use

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

Parenteral medicine products should be inspected visually for particular matter and discolouration prior to the administration whenever solution and container permit. Do not administer unless solution is clear and seal is intact.

To open - Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilisation process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing the inner bag firmly. If leaks are found, discard solution, as sterility may be impaired. If supplemental medication is desired, follow the directions below.

Preparation for Administration -

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication -

Warning: Additives may be incompatible. Those additives known to be incompatible should not be used. Complete information is not available. Consult with a pharmacist, if available. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Plasma-Lyte 56 and 5% Glucose IV Infusion is appropriate. After addition, check for possible colour change and/or the appearance of precipitates, insoluble complexes or crystals. The instructions for use of the medication to be added and other relevant literature must be consulted.

If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

To add medication before solution administration

1. Prepare medication site.
2. Using a syringe with a 0.63 to 0.80mm needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using a syringe with a 0.63 to 0.80mm needle, puncture resealable medication port and inject.
4. Remove container from IV pole and turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly
7. Return container to in-use position and continue administration.

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used containers.

Overdosage

If overdosage is suspected (through the monitoring of electrolytes, especially sodium and potassium), administration of the medicine should be discontinued and the patient observed closely.

Excessive administration of Plasma-Lyte 56 and 5% Glucose IV Infusion may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalaemia as well as a decrease in ionised serum calcium and magnesium (See **Precautions**).

An excessive volume of Plasma-Lyte 56 and 5% Glucose IV Infusion may lead to fluid and sodium overload with a risk of oedema (peripheral and/or pulmonary) particularly when renal sodium excretion is impaired (See **Precautions**).

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with severe renal impairment (See **Precautions**).

Excessive administration of magnesium many lead to hypermagnesaemia (See **Precautions**).

Excessive administration of glucose-containing solution may lead to hyperglycaemia, hyperosmolarity, osmotic diuresis and dehydration.

When assessing an overdose, any additives in the solution must also be considered. The effect of overdose may require immediate medical attention and treatment.

Presentation and storage conditions

Plasma-Lyte 56 with 5% Glucose IV Infusion in Viaflex plastic containers is available as shown below:

Code	Size (mL)	AUST R
AHB2574	1000	19441

Storage Condition
Store below 30°C.
Do not freeze.

Name and address of the sponsor

Baxter Healthcare Pty Ltd
1 Baxter Drive
Old Toongabbie, NSW 2146.

Poison schedule of the medicine

Unscheduled

Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG)

30 September 1991

Date of the most recent amendment

23 March 2015

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