Product Information

Plasma-Lyte 148 Replacement IV Infusion

Name of the medicine
Plasma-Lyte 148 Replacement IV Infusion (Multiple Electrolyte Injection).

Description
Plasma-Lyte 148 Replacement IV Infusion is a sterile, clear, nonpyrogenic isotonic solution in a single dose container for intravenous administration.

Each 1000mL of Plasma-Lyte 148 Replacement IV Infusion contains:

Sodium Chloride	5.26g
Sodium Gluconate	5.02g
Sodium Acetate	3.68g
Potassium Chloride	370mg
Magnesium Chloride	300mg
Hydrochloric acid	pH adjustment
Water for Injections	q.s. to 1000mL
pH range	4.0 to 6.5
Approximate Osmolality	294 mOsm
Approximate Kilojoules	66 kJ

Plasma-Lyte 148 Replacement IV Infusion when administered intravenously is a source of water, electrolytes, and calories. It contains no antimicrobial agents. The osmolalrity is 294 mOsmol/L (calc). Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage.

Each 1000mL of Plasma-Lyte 148 Replacement IV Infusion has an ionic concentration of:

Sodium	140 mmol
Potassium	5 mmol
Magnesium	1.5 mmol
Chloride	98 mmol
Acetate	27 mmol
Gluconate	23 mmol

Pharmacology
Plasma-Lyte 148 Replacement IV Infusion is a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Plasma-Lyte 148 Replacement IV Infusion produces a metabolic alkalinising effect. Acetate and gluconate ions are metabolised ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications

Plasma-Lyte 148 Replacement IV Infusion is indicated as a source of water and electrolytes or as an alkalinising agent.

Contraindications

- Plasma-Lyte 148 Replacement IV infusion is contraindicated in patients with a known hypersensitivity to the product.

Precautions

Plasma-Lyte 148 Replacement IV Infusion is not indicated for

- the treatment of hypochloremic hypokalaemic alkalosis and should be used with caution, in patients with hypochloremic hypokalaemic alkalosis.
- the primary treatment of severe metabolic acidosis.
- hypomagnesaemia.

Although Plasma-Lyte 148 Replacement IV Infusion has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium deficiency; therefore, it should not be used for correction of severe potassium deficiency.

Plasma-Lyte 148 Replacement 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.

Plasma-Lyte 148 Replacement IV Infusion should be administrated with particular caution, if at all to patients with conditions that may cause sodium retention, fluid overload and oedema.

Plasma-Lyte 148 Replacement IV Infusion should be used with caution if at all, in patients with hyperkalemia or conditions predisposing to hyperkalemia (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 148 Replacement IV Infusion should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate 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 148 Replacement IV Infusion can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration /hypervolemia, congested states, including pulmonary congestion and oedema, and 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.

In patients with diminished renal function, administration of Plasma-Lyte 148 Replacement IV Infusion may result in sodium and/or potassium or magnesium retention.

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 warrants such evaluation.

Plasma-Lyte 148 Replacement 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.

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with Plasma-Lyte 148 Replacement 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.

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

Plasma-Lyte 148 Replacement IV Infusion should be administered with particular caution, if at all, to hypervolemia or overhydrated patients.

Plasma-Lyte 148 Replacement IV Infusion should be administered with particular caution, if at all, to patients with conditions that may cause sodium retention, fluid overload and edema, such as patients with primary hyperaldosteronism, secondary hyperaldosteronism (associated with, for example, hypertension, congestive heart failure, renal artery stenosis, or nephrosclerosis), or preeclampsia.

Plasma-Lyte 148 Replacement 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 148 Replacement IV Infusion should be administered with particular caution, if at all, to patients with hypocalcaemia.

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 results 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)

There are no adequate data from the use of Plasma-Lyte 148 Replacement IV Infusion in pregnant women. The potential risks and benefits for each specific patient should be carefully considered before using Plasma-Lyte 148 Replacement IV Infusion in pregnant women.

Use in Lactation
There are no adequate data from the use of Plasma-Lyte 148 Replacement IV Infusion in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using Plasma-Lyte 148 Replacement IV Infusion in lactating women.

Paediatric Use
Safety and effectiveness of Plasma-Lyte 148 Replacement 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.

Use in the elderly
Clinical studies of Plasma-Lyte 148 Replacement 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 elder 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 148 Replacement IV Infusion have not been performed to evaluate carcinogenic potential.

Genotoxicity
Studies with Plasma-Lyte 148 Replacement IV Infusion have not been performed to evaluate mutagenic potential.

Effects on fertility
Studies with Plasma-Lyte 148 Replacement 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.

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. Solutions 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 materials.

Interactions with other medicines

Caution must be exercised in the administration of Plasma-Lyte 148 Replacement 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 148 Replacement IV Infusion to patients treated with drugs for which renal elimination is pH dependent. Due to its alkalinising effect (formation of bicarbonate), Plasma-Lyte 148 Replacement 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 (e.g. ephedrine, pseudoephedrine, quinidine or dextroamphetamine (dexamphetamine) sulfate may be decreased.

Because of its potassium content, Plasma-Lyte 148 Replacement 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, angiontensin II receptor antagonists or the immunosuppressant tacrolimus and cyclosporine.

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
	Hypervolemia
	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 manifestation (tachycardia, palpitations, chest pain, chest discomfort, dyspnoea, respiratory rate increased, flushing, hyperaemia, asthenia, feeling abnormal, piloerection, oedema peripheral and pyrexia.

General Disorders and Administration Site Conditions:
Infusion site reactions e.g. infusion site pain and burning sensation.

Other adverse reactions reported with Plasma-Lyte products with Glucose are:

- other manifestations of hypersensitivity/infusion reactions including hypotension, wheezing, urticaria, cold sweat and chills
- hyperkalaemia

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 depend 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.

Each Viaflex container is for single patient use only.

Parenteral medicine products should be inspected visually for particulate matter and discolouration prior to the administration whenever solution and container permit.

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

Additives may be incompatible. Complete information is not 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 148 Replacement 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.

Those additives known to be incompatible should not be used. Consult with a pharmacist, if available. 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.

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 complete.

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

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 148 Replacement 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 148 Replacement 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 PREAUTIONS

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

Presentation and storage conditions

Plasma-Lyte 148 Replacement IV Infusion in Viaflex plastic containers is available as shown below:

Code	Size (mL)	AUST R
AHB2533	500	19439
AHB2534	1000	48512

Storage condition
Store product below 30°C

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)

AUST R 19439	30 September 1991
AUST R 48512	21 April 1994

Date of the most recent amendment
17 September 2013

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