1 PLASMALYTE 56 IN 5% GLUCOSE (solution for infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Each 1000mL of **Plasmalyte 56 in 5% Glucose** infusion solution contains:

Glucose, anhydrous	50g
Sodium chloride	2.34g
Potassium acetate	1.28g
Magnesium acetate tetrahydrate	320mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Plasmalyte 56 in 5% Glucose infusion solution, a multiple electrolyte with glucose injection, is a sterile, clear, nonpyrogenic hypertonic solution in a single dose container for intravenous administration. It contains no antimicrobial agents. The approximate osmolality is 401mOsmol/kg. An injection with an osmolality within the range of 250 to 350mOsm/kg is considered to be isotonic. **Plasmalyte 56 in 5% Glucose** infusion solution is a hypertonic solution. Administration of substantially hypertonic solutions may cause vein damage.

Solution properties

pH range	3.5 to 6.0
Approximate Osmolality	401mOsm/kg
Approximate Kilojoules	835kJ

Each 1000mL of **Plasmalyte 56 in 5% Glucose** infusion solution has an ionic concentration of:

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Plasmalyte 56 in 5% Glucose infusion solution is indicated as a source of water, electrolytes and calories or as an alkalinising agent.

4.2 Dose and method of administration

Dosage

As directed by the physician. 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. All injections in Viaflex plastic containers are intended for intravenous administration using sterile equipment.

As reported in the literature, the dosage, volume and 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 (see section 4.4/Paediatric use).

For directions for use see section 6.6.

Preparation for administration

Plasmalyte 56 in 5% Glucose infusion solution is a sterile preparation. Thus, aseptic technique must be applied throughout the administration.

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

To add medication

Warning: Additives may be incompatible. Those additives known to be incompatible should not be used. 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 Plasmalyte 56 in 5% Glucose infusion solution 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/or 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.

4.3 Contraindications

Plasmalyte 56 in 5% Glucose infusion solution is contraindicated in patients with a known hypersensitivity to the product. Solutions containing glucose may be contraindicated in patients with known allergy to corn or corn products.

Plasmalyte 56 in 5% Glucose infusion solution must not be used in patients with clinically significant hyperglycaemia.

4.4 Special warnings and precautions for use

Plasmalyte 56 in 5% Glucose infusion solution is not indicated for:

- The treatment of hypochloraemic hypokalaemic alkalosis, and should be used with caution, if at all, in patients with hypochloraemic hypokalaemic alkalosis.
- The primary treatment of severe metabolic acidosis.
- The treatment of hypomagnesaemia.

Plasmalyte 56 in 5% Glucose infusion solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo-agglutination or haemolysis.

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with Plasmalyte 56 in 5% Glucose infusion solution. 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.

Hypertonic solution

Plasmalyte 56 in 5% Glucose infusion solution is a hyperosmotic solution, having an osmolality of 401mOsmol/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 e.g. hypochloraemic hypokalaemic alkalosis due to prolonged vomiting, pyloric stenosis, prolonged nasogastric suctioning.

Fluid and/or solute overload and electrolyte disturbances

Depending on the volume and rate of infusion, intravenous administration of Plasmalyte 56 in 5% Glucose infusion solution can cause:

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

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.

Hyponatraemia

Glucose intravenous infusions are usually isotonic solutions. Plasmalyte 56 in 5% Glucose infusion solution has an osmolality of 401mOsm/kg. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolisation. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolise glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatraemia.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterised by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening cerebral injury.

Use in patients with or at risk of hypermagnesaemia

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.

Use in patients with or at risk of alkalosis

Plasmalyte 56 in 5% Glucose infusion solution should be used with particular caution, if at all, in patients with alkalosis or at risk for alkalosis. Excess administration of Plasmalyte 56 in 5% Glucose infusion solution may result in metabolic 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.

Use in patients with hypervolaemia or overhydration, or conditions that cause sodium retention and oedema

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.

Plasmalyte 56 in 5% Glucose infusion solution should be administered with particular caution, to hypervolaemic or overhydrated patients.

Plasmalyte 56 in 5% Glucose infusion solution 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.

Use in patients with hypocalcaemia

Plasmalyte 56 in 5% Glucose infusion solution contains no calcium and an increase in plasma pH due to its alkalinising effect may lower the concentration of ionised (not protein-bound) calcium.
Plasmalyte 56 in 5% Glucose infusion solution should be administered with particular caution, if at all, to patients with hypocalcaemia.

Use in patients with or at risk of hyperkalaemia

Plasmalyte 56 in 5% Glucose infusion solution 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.

Use in patients with severe renal impairment

In patients with diminished renal function, administration of Plasmalyte 56 in 5% Glucose infusion solution may result in sodium and/or potassium or magnesium retention.

Use in patients with or at risk of hyperglycaemia

Plasmalyte 56 in 5% Glucose infusion solution 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.

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 (see section 4.4).

Risk of air embolism

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.

Other

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.

Use in the elderly

Clinical studies of Plasmalyte 56 in 5% Glucose infusion solution 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 medicinal therapy.

Paediatric use

Safety and effectiveness of Plasmalyte 56 in 5% Glucose infusion solution 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 enterocolitits, 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.

Effect on laboratory tests

The effect of this medicine on laboratory tests has not been established.

4.5 Interaction with other medicines and other forms of interaction

Plasmalyte 56 in 5% Glucose infusion solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo-agglutination or haemolysis.

Caution must be exercised in the administration of Plasmalyte 56 in 5% Glucose infusion solution to patients treated with medicines that may increase the risk of sodium and fluid retention such as corticosteroids or corticotropin.

Caution is advised when administering Plasmalyte 56 in 5% Glucose infusion solution to patients treated with medicines for which renal elimination is pH dependent. Due to its alkalinising effect (formation of bicarbonate), Plasmalyte 56 in 5% Glucose infusion solution may interfere with the elimination of such medicines:

- Renal clearance of acidic medicines such as salicylates, barbiturates and lithium may be increased.
- Renal clearance of alkaline medicines such as sympathomimetics (e.g. ephedrine, pseudoephedrine), quinidine or dextroamphetamine (dexamphetamine) sulfate may be decreased.

Because of its potassium content, Plasmalyte 56 in 5% Glucose infusion solution 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.

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

Caution is advised when administering **Plasmalyte 56 in 5% Glucose** infusion solution to patients treated with medicines leading to an increased vasopressin effect. The below listed medicines increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatraemia following treatment with IV fluids. (See sections 4.4 and 4.8):

- Medicines stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Medicines potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDS), cyclophosphamide.
- Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering **Plasmalyte 56 in 5% Glucose** infusion solution to patients treated with medicines that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g., oxcarbazepine). See section 6.2.

4.6 Fertility, pregnancy and lactation

Fertility

Studies with **Plasmalyte 56 in 5% Glucose** infusion solution have not been performed to evaluate effect on fertility.

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 **Plasmalyte 56 in 5% Glucose** infusion solution.

Use in breast feeding

There are no adequate data from the use of **Plasmalyte 56 in 5% Glucose** infusion solution in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using **Plasmalyte 56 in 5% Glucose** infusion solution in lactating women.

4.7 Effects on ability to drive and use machines

There is no information on the effects of **Plasmalyte 56 in 5% Glucose** on the ability to drive or operate an automobile or other heavy machinery.

4.8 Undesirable 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 Plasmalyte products and Plasmalyte 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 (e.g. burning sensation).

Other adverse reactions

Other adverse reactions reported with Plasmalyte 56 in 5% Glucose infusion solution or other similar products are:

- Other manifestations of hypersensitivity/infusion reactions including anaphylactoid reaction and the following manifestations: tachycardia, palpitations, chest pain, respiratory rate increased, feeling abnormal, piloerection, and oedema peripheral and infusion site pain.
- Hyponatraemia
- Hyponatraemic encephalopathy.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continuing monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphv.otago.ac.nz/reporting/

4.9 Overdose

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 Plasmalyte 56 in 5% Glucose infusion solution may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalaemia as well as a decrease in ionised serum calcium and magnesium (see section 4.4).

An excessive volume of Plasmalyte 56 in 5% Glucose infusion solution may lead to fluid and sodium overload with a risk of oedema (peripheral and/or pulmonary) particularly when renal sodium excretion is impaired (see section 4.4).

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with severe renal impairment (see section 4.4).

Excessive administration of magnesium many lead to hypermagnesaemia (see section 4.4).

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.

For advice on the management of overdose please contact the National Poisons Centre on phone number: 0800 764 766 [0800 POISON] in New Zealand (or 131126 in Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Electrolytes with carbohydrates.

ATC Code

B05BB02.

Mechanism of action

Plasmalyte 56 in 5% Glucose infusion solution is a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Plasmalyte 56 in 5% Glucose infusion solution produces a metabolic alkalinising effect. Acetate ions are metabolised ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Physiochemical properties

Sodium chloride

Molecular formula: NaCl
Molecular Weight: 58.44
Appearance: colourless or white crystal
Solubility: freely soluble in water
CAS No.: 7647-14-5

Potassium acetate

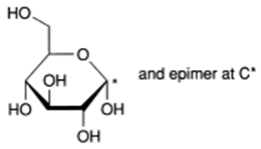
Molecular formula: $C_2H_3O_2K$
Molecular Weight: 98.15
Appearance: colourless crystal or white powder
Solubility: soluble in water
CAS No.: 4251-29-0

Magnesium acetate tetrahydrate

Molecular formula: $C_4H_{14}O_8Mg$
Molecular Weight: 214.45
Appearance: white hygroscopic crystals
Solubility: soluble in water
CAS No.: 16674-78-5

Glucose (D-(+)glucopyranose)

Structural formula:



Molecular formula: $C_6H_{12}O_6$
Molecular Weight: 180.2
Appearance: a white or almost white, crystalline powder
Solubility: freely soluble in water, sparingly soluble in ethanol (96%)
CAS No.: 50-99-7

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Carcinogenicity

Studies with **Plasmalyte 56 in 5% Glucose** infusion solution have not been performed to evaluate carcinogenic potential.

Genotoxicity

Studies with **Plasmalyte 56 in 5% Glucose** infusion solution have not been performed to evaluate mutagenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment).
Water of injection, q.s. to 1000mL.

6.2 Incompatibilities

Additives may be incompatible. As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition. Those additives known to be incompatible should not be used. Consult with a pharmacist, if available.

6.3 Shelf life

24 months from date of manufacture. The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store at or below 30°C. Do not freeze.

6.5 Nature and contents of container

Plasmalyte 56 in 5% Glucose infusion solution in Viaflex plastic containers is available as shown below:

Code	Size (mL)	TT50-
AHB2574	1000	2332/2

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

Directions for use of Viaflex plastic container

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 (see section 4.4/Risk of air embolism).

Parenteral medicine products should be inspected visually for particulaate 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 in section 4.2/To add medication.

7 MEDICINE SCHEDULE

General Sale Medicine.

8 SPONSOR

Plasmalyte 56 in 5% Glucose infusion solution is distributed in New Zealand by:

Baxter Healthcare Ltd
33 Vestey Drive
Mt Wellington
Auckland 1060.

Baxter Healthcare Ltd
PO Box 14 062
Panmure
Auckland 1741

Phone (09) 574 2400.

Plasmalyte 56 in 5% Glucose infusion solution is distributed in Australia by:

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

9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:
28 November 1974.

10 DATE OF REVISION OF THE TEXT

9 July 2019.

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Updated ingredient names as per product label and IHIN and put in quantity order.
4.2	Removal of redundant information and text relocated.
4.3	Moved paragraph for improved readability.
4.4	Added hyponatraemia information, repositioned paragraphs and added subheadings in alignment with CCSI.
4.5	Added information relating to vasopressin effect.
4.8	Other adverse reactions updated.
5	Added physiochemical properties.
All	Text arranged to be in alignment and consistent with other Plasmalyte Data Sheets.

Based on Australian PI most recent amendment 3 June 2019; and CCSI 420 2018 03July.

Please refer to the Medsafe website (www.medsafe.govt.nz) for most recent data sheet.