

NEW ZEALAND DATA SHEET

1 PLASMALYTE 148, pH 7.4 (solution for infusion)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Each 1000mL of **Plasmalyte 148, pH 7.4** infusion solution contains:

Sodium chloride	5.26g
Sodium gluconate	5.02g
Sodium acetate trihydrate	3.68g
Potassium chloride	370mg
Magnesium chloride hexahydrate	300mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Plasmalyte 148, pH 7.4 infusion solution, a multiple electrolyte injection, is a sterile, clear, nonpyrogenic isotonic solution in a single dose container for intravenous administration. It contains no antimicrobial agents. The approximate osmolality is 271mOsm/kg. An injection with an osmolality within the range of 250 to 350mOsm/kg is considered to be isotonic. Administration of substantially hypertonic solutions may cause vein damage.

Solution properties

pH range	6.5 to 8.0.
Approximate Osmolality	271mOsm/kg
Approximate Kilojoules	66kJ

Plasmalyte 148, pH 7.4 infusion solution, when administered intravenously, is a source of water, electrolytes, and calories.

Each 1000mL of **Plasmalyte 148, pH 7.4** infusion solution has an ionic concentration of:

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Plasmalyte 148, pH 7.4 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.

NEW ZEALAND DATA SHEET

For directions for use see section 6.6.

Preparation for administration

Plasmalyte 148, pH 7.4 infusion solution is 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. Additives known or determined to be incompatible must 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 148, pH 7.4** 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 medications, 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. Evaluate 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 148, pH 7.4 infusion solution is contraindicated in patients with a known hypersensitivity to the product.

NEW ZEALAND DATA SHEET

4.4 Special warnings and precautions for use

Plasmalyte 148, pH 7.4 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.

Although **Plasmalyte 148, pH 7.4** infusion solution 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.

Hypersensitivity reactions

Hypersensitivity/infusion reactions, including anaphylactoid reactions, have been reported with **Plasmalyte 148, pH 7.4** 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.

Fluid and/or solute overload and electrolyte disturbances

Depending on the volume and rate of infusion, intravenous administration of **Plasmalyte 148, pH 7.4** infusion solution can cause:

- Fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration/hypervolemia, 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

Monitoring of serum sodium is important for all fluids. 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 148, pH 7.4 infusion solution 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.

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.

NEW ZEALAND DATA SHEET

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 148, pH 7.4 infusion solution should be administered with particular caution, to hypervolaemic or overhydrated patients.

Plasmalyte 148, pH 7.4 infusion solution should be administered with particular caution, if at all, to patients with conditions that may cause 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.

Plasmalyte 148, pH 7.4 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.

Use in patients with hypocalcaemia

Plasmalyte 148, pH 7.4 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 148, pH 7.4** 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 148, pH 7.4 infusion solution should be used with caution, if at all, in patients with hyperkalaemia or 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

Plasmalyte 148, pH 7.4 infusion solution should be administered with particular caution, if at all, to patients with severe renal impairment.

In patients with diminished renal function, administration of **Plasmalyte 148, pH 7.4** infusion solution may result in sodium and/or potassium or magnesium retention.

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.

NEW ZEALAND DATA SHEET

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. 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.

Use in the elderly

Clinical studies of **Plasmalyte 148, pH 7.4** 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 148, pH 7.4** 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.

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 Plasmalyte 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 Plasmalyte solutions should be interpreted cautiously by other diagnostic methods.

4.5 Interaction with other medicines and other forms of interaction

Caution must be exercised in the administration of **Plasmalyte 148, pH 7.4** 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 148, pH 7.4** infusion solution to patients treated with medicines for which renal elimination is pH dependent. Due to its alkalinising effect (formation of bicarbonate), **Plasmalyte 148, pH 7.4** 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.

NEW ZEALAND DATA SHEET

Because of its potassium content, **Plasmalyte 148, pH 7.4** 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, angiotensin II receptor antagonists or the immunosuppressant tacrolimus and cyclosporine.

Caution is advised when administering **Plasmalyte 148, pH 7.4** 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 148, pH 7.4** 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 148, pH 7.4** infusion solution have not been performed to evaluate effect on fertility.

Use in pregnancy (no category)

There are no adequate data from the use of **Plasmalyte 148, pH 7.4** infusion solution in pregnant women. Physicians should carefully consider the potential risks and benefits for each specific patient before administering **Plasmalyte 148, pH 7.4** infusion solution.

Use in breast feeding

There are no adequate data from the use of **Plasmalyte 148, pH 7.4** infusion solution in lactating women. The potential risks and benefits for each specific patient should be carefully considered before using **Plasmalyte 148, pH 7.4** infusion solution in lactating women.

4.7 Effects on ability to drive and use machines

There is no information on the effects of **Plasmalyte 148, pH 7.4** infusion solution on the ability to 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.

NEW ZEALAND DATA SHEET

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: 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 reaction (e.g. infusion site pain and burning sensation).

Other adverse reactions

Other adverse reactions reported with **Plasmalyte 148, pH 7.4** infusion solution or other similar products are:

- Other manifestations of hypersensitivity/infusion reactions including hypotension, wheezing, urticaria, cold sweat and chills.
- Hyperkalaemia.
- 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 148, pH 7.4** 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.

An excessive volume of **Plasmalyte 148, pH 7.4** 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.

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with severe renal impairment.

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

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).

NEW ZEALAND DATA SHEET

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Electrolytes

ATC Code

B05BB01.

Mechanism of action

Plasmalyte 148, pH 7.4 infusion solution is a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

Plasmalyte 148, pH 7.4 infusion solution produces a metabolic alkalising effect. Acetate and gluconate ions are metabolised ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Physiochemical properties

Sodium chloride

Molecular formula: NaCl

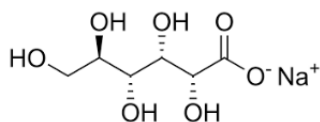
Molecular Weight: 58.44

Appearance: colourless or white crystal

Solubility: freely soluble in water

CAS No.: 7647-14-5

Sodium gluconate (sodium D-gluconate)



Molecular formula: C₆H₁₁NaO₇

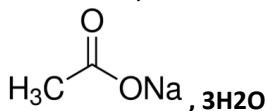
Molecular Weight: 218.14

Appearance: white to off white crystalline powder

Solubility: very soluble in water; sparingly soluble in alcohol; insoluble in ether

CAS No.: 527-07-1

Sodium acetate trihydrate



Molecular formula: C₂H₃NaO₂·3H₂O

Molecular Weight: 136.1

Appearance: white crystalline solid

Solubility: hygroscopic, very soluble in water; moderately soluble in ethanol

CAS No.: 6131-90-4

Potassium chloride

Molecular formula: KCl

Molecular Weight: 74.55

Appearance: colourless or white crystal

Solubility: freely soluble in water

CAS No.: 7447-40-7

NEW ZEALAND DATA SHEET

Magnesium chloride hexahydrate

Molecular formula: MgCl₂.6H₂O

Molecular Weight: 203.31

Appearance: white or colourless crystalline solid

Solubility: very soluble in water

CAS No.: 7791-18-6

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Carcinogenicity

Studies with **Plasmalyte 148, pH 7.4** infusion solution have not been performed to evaluate carcinogenic potential.

Genotoxicity

Studies with **Plasmalyte 148, pH 7.4** infusion solution have not been performed to evaluate mutagenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (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 148, pH 7.4 infusion solution in Vialflex plastic containers is available as shown below:

Code	Size (mL)	TT50-
AHB2543	500	2332/5
AHB2544	1000	2332/5

Not all pack sizes may be marketed.

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 Vialflex plastic containers

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 (see section 4.4/Risk of air embolism).

NEW ZEALAND DATA SHEET

Parenteral medicine products should be inspected visually for particulate 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 148, pH 7.4 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 148, pH 7.4 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:
12 July 1989.

10 DATE OF REVISION OF THE TEXT

9 July 2019.

NEW ZEALAND DATA SHEET

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Updated ingredient names as per IHIN.
4.2	Removal of redundant information.
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.
6.2	Added incompatibilities information.
All	Text arranged to be in alignment and consistent with other Plasmalyte Data Sheets.

Based on Australian PI most recent amendment 30 May 2019; and CCSI419 2018 03July.

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

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