

# NEW ZEALAND DATA SHEET

## 1 Sodium Chloride (infusion, solution)

**Sodium Chloride** 0.45% Infusion, solution

**Sodium Chloride** 0.9% Infusion, solution

**Sodium Chloride** 3% Infusion, solution.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### *Active ingredient*

Sodium chloride, in Water for Injection.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Infusion, solution in Viaflex plastic bag (for intravenous infusion).

**Sodium Chloride** infusion solution preparations are sterile, non-pyrogenic solutions of sodium chloride in Water for Injection.

The preparations do not contain an antimicrobial agent or added buffer, and have a pH of 4.0 – 7.0.

**Sodium Chloride** 0.9% infusion solution is isotonic, **Sodium Chloride** 3% (1026mOsmol/L) is hypertonic and **Sodium Chloride** 0.45% (154mOsmol/L) is hypotonic, as indicated by their osmolarities. The concentration of sodium chloride in each preparation and their osmolarities are shown in Table 1 (see section 6.5). In a dilute condition, osmolarity/L is approximately the same as osmolality/kg.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

**Sodium Chloride** 0.9% infusion solution is indicated for extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss, and for restoring or maintaining the concentration of sodium and chloride ions.

Hypertonic **Sodium Chloride** 3% infusion solution is used in the management of severe sodium chloride depletion when electrolyte restoration is required.

Hypotonic **Sodium Chloride** 0.45% infusion solution is mainly used as a hydrating agent solution.

### 4.2 Dose and method of administration

#### *General directive*

**Sodium Chloride** (0.45%, 0.9%, 3%) infusion solution is for intravenous infusion. To be used as directed by the doctor.

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.

Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. The solution should be clear and free from particles. Do not administer unless solution is clear and seal is intact.

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Additives may be incompatible, see section 6.2. Suitability of potential additives has not been demonstrated. Complete information is not available. Those additives known to be incompatible should not be used. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of **Sodium Chloride** infusion solution is appropriate. The instructions for use of the medication to be added and other relevant literature must be consulted. Consult with a pharmacist, if available. If in the informed judgment of the doctor, it is deemed advisable to introduce additives, use aseptic technique.

Mix thoroughly when additives have been introduced. After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals. Do not store solutions containing additives. The stability of this product when mixed with additives has not been demonstrated (see sections 4.4 and 4.5).

When other electrolytes or medicines are added to this solution, the dosage and the infusion rate will also be dictated by the dose regimen of the additions.

The product should be used for one patient on one occasion only. Any unused portion should be discarded.

Hypertonic solutions are preferably administered via a large central vein. If hypertonic solutions are administered peripherally, a large arm vein should be used and, if possible, the injection site should be altered daily. IV infusion of **Sodium Chloride** 3% infusion solution should not exceed 100mL/hr and serum electrolyte concentrations should be determined to assess the need for further administration.

### ***Directions for use of Viaflex plastic container***

**Warning:** Do not connect flexible 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.

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.

### ***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 inner bag firmly. If leaks are found, discard the product as sterility may be impaired. If supplemental medication is desired, follow directions below.

### ***Preparation for administration***

**Sodium Chloride** infusion solution is a sterile preparation. Thus, aseptic technique must be applied throughout administration.

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

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## ***To add medication***

**Warning:** Additives may be incompatible, see sections 4.4, 4.5 and 6.2.

## ***To add medication before solution administration***

Supplemental medication may be added with needle through the medication injection port. To proceed, swab medication site (port) with alcohol swab. Using a syringe with 0.63 to 0.80mm needle, puncture resealable medication port and inject. 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***

Close clamp on the set. Prepare medication port. Using syringe with 0.63 to 0.80mm needle, puncture resealable medication port and inject. Remove container from IV pole and/or turn to upright position. Evaluate both ports by squeezing them while container is in the upright position. Mix solution and medication thoroughly. Return container to in use position and continue administration.

The solutions contain no antimicrobial agents, and are for single use in only one patient. Unused portions must be discarded.

## **4.3 Contraindications**

The use of **Sodium Chloride** infusion solution requires careful evaluation of risks and benefits by the attending physician. It must not be used in the following conditions unless the physician has determined that potential benefits outweigh risks:

- congestive heart failure,
- severe impairment of renal function and
- clinical states in which there exists oedema with sodium retention (see section 4.4).

**Sodium Chloride** 3% infusion solution is contraindicated for electrolyte replacement in the presence of increased, normal, or only slightly decreased serum electrolyte concentrations.

## **4.4 Special warnings and precautions for use**

**Warning:** Care should be exercised regarding possible incompatibility outcomes resulting from the interaction between the plastic container (Viaflex® plastic bag fabricated from a specially formulated polyvinyl chloride, PL 146 Plastic) or active ingredients and the added therapeutic substances (see section 4.2). Small amounts of the components, e.g. di-2-ethylhexyl phthalate (DEHP) up to 5ppm, may leach out during its shelf life. During the sterilisation step a small amount of hydrochloric acid may leach out resulting in a slightly acidic solution (see section 2). The safety of the Viaflex plastic bag containers has been shown in tests with animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies.

In a dilute condition, osmolarity/L is approximately the same as osmolality/kg. As shown in Table 1 (section 6.5), **Sodium Chloride** 3% infusion solution is hypertonic as indicated by its osmolarity, 1026mOsmol/L. The administration of substantially hypertonic solution may lead to a wide variety of complications. This includes crenation (cell shrinkage) of red blood cells and general cellular dehydration. Thus, it should be administered through a large central vein, for rapid dilution of the hypertonic solution (see section 4.2).

In contrast, the **Sodium Chloride** 0.45% infusion solution is hypotonic (154mOsmol/L). It may be infused with caution by peripheral vein administration, but may lead to cell swelling or oedema.

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## ***Hypersensitivity reactions***

Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, and pruritus, have been reported with 0.9% sodium chloride.

Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

## ***Hyponatraemia***

Monitoring of serum sodium is important for all fluids, particularly for hypotonic fluids (such as **Sodium Chloride** 0.45% infusion solution). 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.

The infusion of solutions with sodium (0.45% or < 0.9%) may result in hyponatraemia, which may warrant close clinical monitoring. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterised by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk for hyponatraemia is increased in children, elderly patients, women, postoperatively, persons with psychogenic polydipsia, patients treated with medications that increase the risk of hyponatraemia (such as certain antiepileptic and psychotropic medications).

The risk for developing hyponatraemic encephalopathy is increased in paediatric patients ( $\leq 16$  years of age), women (in particular pre-menopausal women), patients with hypoxemia and in patients with underlying central nervous system disease.

## ***Fluid and/or solute overload and electrolyte disturbances***

Clinical evaluation and appropriate laboratory determinations are essential to monitor renal function, changes in fluid balance, electrolyte concentration and acid-base balance.

Depending on the volume and rate of infusion, intravenous administration of sodium chloride may cause:

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

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

Clinical evaluation and periodic laboratory determinations may be 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. Thus, caution should be exercised in patients with hypertension, heart failure, cerebral oedema, renal disease, pulmonary or peripheral oedema, pre-eclampsia, liver cirrhosis, conditions associated with sodium retention, and in geriatric patients, and infants.

Sodium chloride infusions should be used with caution in patients receiving corticosteroids or corticotrophin, because of potential sodium and fluid retention.

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Sodium chloride infusions should be used with particular caution, if at all, in patients with or at risk for:

- hypernatraemia,
- hyperchloraemia,
- metabolic acidosis,
- hypervolaemia and
- conditions that may cause sodium retention, fluid overload and oedema (central and peripheral).

Its use may result in electrolyte abnormalities, including hypokalaemia or hyperkalaemia, see sections 4.8 and 4.9.

Rapid correction of hyponatraemia or hypernatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

### ***Use in Renal Impairment***

Sodium chloride infusions should be administered with particular caution, if at all, to patients with severe renal impairment. In such patient's administration of solutions containing high concentration of sodium chloride may result in sodium retention.

### ***Use in the elderly***

Geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant pharmaceutical therapy and should be taken into consideration for selecting the type of infusion solution and the volume/rate of infusion. In elderly patients, the risk of hyponatraemia is increased.

The infusion of hypotonic fluids together with the non-osmotic secretion of anti-diuretic hormone (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.

### ***Paediatric use***

Rapid correction of hyponatraemia or hypernatraemia is potentially dangerous (risk of serious neurologic complications). Dosage, rate and duration of administration should be determined by a physician experienced in intravenous fluid therapy.

Plasma electrolyte concentrations should be closely monitored in the paediatric population because of their impaired ability to regulate fluids and electrolytes.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatraemia. Acute hyponatremia can lead to acute hyponatraemic encephalopathy (brain oedema) characterised by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

### ***Effects on laboratory tests***

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

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## 4.5 Interaction with other medicines and other forms of interaction

**Sodium Chloride** infusion solution should not be administered simultaneously with blood products through the same administration set, because of the possibility of pseudo-agglutination or haemolysis.

If **Sodium Chloride** 0.45% or 0.9% infusion solution is used as a vehicle for a medication delivery, a thorough review of the prescribing information document(s) of such medicine(s) should be made to ensure that no incompatibility might occur. Salting out, i.e., a precipitation of organic base pharmaceutical may occur in the presence of salt.

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be:

- Increased during administration of **Sodium Chloride** 0.9% or 3% infusion solutions resulting in decreased lithium levels.
- Decreased in presence of hyponatraemia. Administration of **Sodium Chloride** 0.45% infusion solution may result in increased lithium levels.

Caution is advised when administering sodium chloride infusions 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 intravenous fluids (see sections 4.4 and 4.8).

- Medications stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.
- Medications 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 sodium chloride infusions to patients treated with medicines that may increase the risk of hyponatraemia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

Sodium chloride infusions should be used with caution in patients receiving corticosteroids or corticotropin, because of potential sodium and fluid retention.

## 4.6 Fertility, pregnancy and lactation

### *Fertility*

No data available.

### *Use in pregnancy (Category A)*

There are no adequate and well-controlled studies of sodium chloride infusions in animals or in pregnant women. However, **Sodium Chloride** infusion solution contains no components known to have adverse effects on the foetus at physiological concentrations. Physicians should carefully consider the potential risks and benefits for each specific patient before administering **Sodium Chloride** infusion solution.

### *Use in lactation*

There are no adequate data from the use of sodium chloride infusion solutions in lactating women.

Following intravenous administration, a fraction of sodium and chloride ions is expected to be excreted into human milk. However, at physiological concentrations, neither of these ions is known to have adverse effects on a breastfeeding baby.

Physicians should carefully consider the potential risks and benefits for each specific patient before administering **Sodium Chloride** infusion solution.

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## 4.7 Effects on ability to drive and use machines

There is no information on the effects of sodium chloride on the ability to operate an automobile or other heavy machinery.

## 4.8 Undesirable effects

Adverse effects, which may occur because of the solution or the technique of administration, include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolaemia.

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.

Inappropriate use of sodium chloride infusion may cause fluid or solute overload resulting in electrolyte abnormalities, overhydration, congestive conditions, including central, peripheral or pulmonary oedema, electrolyte imbalances and acid-base imbalance.

### *Post-marketing adverse reactions*

The following adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then, where feasible, by Preferred Term in order of severity.

IMMUNE SYSTEM DISORDERS: Hypersensitivity/infusion reactions, including hypotension, pyrexia, tremor, chills, urticaria, rash, pruritus.

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions, such as thrombosis, phlebitis, irritation, infusion site erythema, injection site streaking, burning sensation, infusion site urticaria.

### *Other adverse reactions/class reactions*

The following adverse reactions have been reported with other similar products:

- hypernatraemia,
- hyperchloraemic metabolic acidosis,
- hyponatraemia, which may be symptomatic,
- hyponatraemic encephalopathy and
- hyperchoreaemia (for products containing > 0.9% sodium chloride).

### *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

Infusion of excess **Sodium Chloride** infusion solution preparations may cause:

- fluid overload,
- sodium overload (which can lead to central and/or peripheral oedema),
- hypernatraemia (0.9% or 3% **Sodium Chloride** infusion solution),
- hyponatraemia (0.9% or 0.45% **Sodium Chloride** infusion solution) and
- other electrolyte abnormalities.

No specific antidotes to this preparation are known.

Should overdose occur, prompt and careful clinical assessment is essential. Treat the symptoms and institute appropriate supportive measures as required.

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When assessing an overdose, any additives in the solution must also be considered.

## ***Symptoms of hypernatraemia***

Hypernatraemia may cause nausea, vomiting, diarrhoea and cramps, reduced salivation and lacrimation, increased thirst, hypotension, and tachycardia.

CNS effects include headache, dizziness, restlessness, weakness, muscle twitching or rigidity, respiratory paralysis, seizures, coma, and death.

## ***Treatment of hypernatraemia***

Treatment usually requires free water replacement. Plasma sodium concentrations should be corrected slowly. If hypernatraemia is severe, IV hypotonic or isotonic saline or 5% glucose may be used to restore normal plasma sodium concentrations at a rate of no more than 10 to 12mmol/L daily (0.5mmol/L per hour). If plasma sodium levels are greater than 200mmol/L or if the patient has renal impairment or is moribund, dialysis may be needed. Diazepam or other appropriate treatment may be required to treat convulsions.

## ***Symptoms of hyponatraemia***

Symptoms may include headache, confusion, nausea, vomiting, somnolence weakness, cerebral oedema, seizures, coma, respiratory arrest, and death.

## ***Treatment of hyponatraemia***

Acute hyponatraemia requires immediate assessment. Symptomatic hyponatraemia associated with plasma sodium concentrations below 120mmol/L may require the administration of intravenous isotonic or hypertonic **Sodium Chloride** infusion solution. A loop diuretic may be required if there is fluid overload. The aim is to render the patient asymptomatic, usually by restoring plasma sodium concentration to between 120mmol/L and 130mmol/L, at a rate of 10 to 12mmol/L in each 24-hour period.

Careful monitoring of plasma sodium concentrations and total body water is essential.

As in hypernatraemia, rapid correction of hyponatraemia is potentially dangerous. If neurological deterioration occurs, further investigation by MRI imaging of brain, including brain stem, is indicated.

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**

<i>Pharmacotherapeutic group</i>	Other IV Solution Additives
<i>ATC Code</i>	B05XX
<i>Chemical name</i>	Sodium chloride
<i>Molecular formula</i>	NaCl
<i>Molecular weight</i>	58.44
<i>Appearance</i>	Colourless or white crystal
<i>Solubility</i>	Freely soluble in water
<i>CAS</i>	7647-14-5

### ***Mechanism of Action***

Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of sodium cation in maintenance of



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acid-base balance, isotonicity and electrodynamic characteristic of the cells. Thus, **Sodium Chloride** infusion solution has a value as a source of water and electrolytes.

## *Clinical trials*

No data available.

## **5.2 Pharmacokinetic properties**

As **Sodium Chloride** infusion solution is administered to the systemic circulation by intravenous infusion, the bioavailability (absorption) of the active components is complete (100%).

## **5.3 Preclinical safety data**

### *Carcinogenicity*

Studies with sodium chloride have not been performed to evaluate carcinogenic potential.

### *Genotoxicity*

Studies with sodium chloride have not been performed to evaluate mutagenic potential.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Water for Injection, q.s.

### **6.2 Incompatibilities**

Additives may be incompatible. Suitability of potential additives has not been demonstrated. Complete information is not available. Those additives known to be incompatible should not be used (see section 4.2).

**Sodium Chloride** infusion solution should not be administered simultaneously with blood products through the same administration set, because of the possibility of pseudo- agglutination or haemolysis (see section 4.5).

### **6.3 Shelf life**

**Sodium Chloride** 0.45% infusion solution:

Bag, plastic 50mL	24 months from date of manufacture.
Bag, plastic 100mL	24 months from date of manufacture.
Bag, plastic 250mL	24 months from date of manufacture.
Bag, plastic 500mL	24 months from date of manufacture.

**Sodium Chloride** 0.9% infusion solution:

Bag, plastic 50mL	18 months from date of manufacture.
Bag, plastic (single) 100mL	18 months from date of manufacture.
Bag, plastic (double) 2 x 100mL	24 months from date of manufacture.
Bag, plastic 250mL	24 months from date of manufacture.
Bag, plastic 500mL	24 months from date of manufacture.
Bag, plastic 1000mL	24 months from date of manufacture.

**Sodium Chloride** 3% infusion solution:

Bag, plastic 1000mL	24 months from date of manufacture.
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The expiry date can be found on the packaging.

### **6.4 Special precautions for storage**

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

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## 6.5 Nature and contents of container

**Sodium Chloride** infusion solutions are supplied in Vialflex plastic bags:

Table 1: Sodium Chloride (0.45%, 0.9%, 3%) infusion solution preparations				
Item code	Name of the active components, concentrations % (mmol/1000mL)	Osmolarity <sup>a</sup> [mOsmol/L]	NZ TT50-registration number	Pack Size* (mL)
AHB1306	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	50mL
AHB1307	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	100mL
AHB1322	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	250mL
AHB1323	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	500mL
AHB1324	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	1000mL
AHB1363	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	50mL x 2
AHB1364	Sodium Chloride 0.9% (154)	308 [300]	5536/4a	100mL x 2
AHB1313	Sodium Chloride 0.45% (77)	154 [150]	5536/4	500mL x 18
AHB1354	Sodium Chloride 3% (513)	1026 [1000]	5536/4b	1000mL

Note: Osmolarities<sup>a</sup> are calculated figures, whilst those in the [bracket] are approximate Osmolalities (mOsmol/kg); **Sodium Chloride** 3% Infusion solution is hypertonic as indicated by the osmolarity of 1026mOsmol/L, whilst **Sodium Chloride** 0.45% Infusion solution is hypotonic.

\* 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.

## 7 MEDICINE SCHEDULE

General Sale Medicine.

## 8 SPONSOR

**Sodium Chloride** 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.

**Sodium Chloride** infusion solution is distributed in Australia by:

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

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## 9 DATE OF FIRST APPROVAL

Date of publication in the New Zealand Gazette of consent to distribute the medicine:

**Sodium Chloride**, 0.45% Infusion, solution: 2 October 1980.

**Sodium Chloride**, 0.9% Infusion, solution: 2 October 1980.

**Sodium Chloride**, 3% Infusion, solution: 2 October 1980.

## 10 DATE OF REVISION OF THE TEXT

14 August 2019.

## SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
2	Removed reference to hydrochloric acid which is already in 4.4.
3	Clarified intravenous infusion.
All	'Drug' replaced with throughout with appropriate term.
4.4 and 4.8	Additional warnings relating to hyponatraemia
4.5	Additional interaction information.

*Based on Australian PI most recent amendment 29 July 2019 and  
CCSI(0.45%)42820180703, CCSI(0.9%)42320180720, and CCSI(3-5%)42920130507.*

*Please refer to the Medsafe website ([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for most recent data sheet.*

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