Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

0.18%w/v Sodium Chloride and 4.0% w/v Glucose Intravenous Infusion BP, (Viaflo Container)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride: 1.80 g/l
Glucose (as monohydrate): 40.00 g/l

Each ml contains 1.8 mg sodium chloride and 40 mg glucose (as monohydrate).
mmol/l (approx): Na+: 30 Cl^-: 30
approximately: 668 kJ/l (or 160 kcal)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Sterile, non-pyrogenic, clear, colourless, aqueous Solution for Infusion.
pH: 3.5-5.5 and osmolarity (approx): 284 m0sm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sodium Chloride 0.18 % and Glucose 4% solution is used in the following indications:

Dehydration treatment due to a moderated loss of sodium and chloride (vomiting, diarrhoea, renal disorders, overuse of diuretics) in cases where a source of energy is required (particularly starvation).

Paediatric Population
This product should only be used in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) for intravenous fluid therapy requiring the use of 0.18% sodium chloride and 4% glucose to maintain fluid and electrolyte balance.

4.2 Posology and method of administration

The choice of the specific sodium chloride and glucose concentration, dosage, volume, rate and duration of administration depends on the age, weight, clinical condition of the patient and concomitant therapy. It should be determined by a physician. For patients with electrolyte and glucose abnormalities and for paediatric patients, consult a physician experienced in intravenous fluid therapy.

Fluid balance, serum glucose, serum sodium and other electrolytes should be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. Sodium Chloride 0.18 % w/v and Glucose 4% w/v solution may become extremely hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications).

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

Adults, older patients and adolescents (age 12 years and over):
The Recommended dosage is 500 ml to 3 L/24h

Administration rate
The infusion rate is usually 40 ml/kg/24h and should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum acute administration rate is 5 mg/kg/min.

Paediatric Population
Use of 0.18% sodium chloride and 4% glucose should be restricted to specialist paediatric settings such as renal, hepatic and cardiac units, high dependency units and intensive care units.

The dosage varies with weight:
0-10 kg body weight: 100 ml/kg/24h
10-20 kg body weight: 1000 ml + (50 ml/kg over 10 kg)/24h
> 20 kg body weight: 1500 ml + (20 ml/kg over 20 kg)/24h.

The administration rate varies with weight:
0-10 kg body weight: 6-8 ml/kg/h
10-20 kg body weight: 4-6 ml/kg/h
> 20 kg body weight: 2-4 ml/kg/h

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycaemia. Therefore the maximum acute administration rate is 10-18 mg/kg/min, depending on the total body mass.

For all patients, a gradual increase of flow rate should be considered when starting administration of glucose containing products.

Method of administration
The administration is performed by intravenous infusion.

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution is hypotonic and hyperosmolar, due to the glucose content.

Precautions to be taken before manipulating or administering the product
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the seal is intact. Administer immediately following the insertion of infusion set.
Do not remove unit from overwrap until ready for use.
The inner bag maintains the sterility of the product.

The solution should be administered with sterile equipment using an aseptic technique.
The equipment should be primed with the solution in order to prevent air entering the system.
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 the administration of the fluid from the secondary container is completed.

Pressurizing 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.

Additives may be introduced before or during infusion through the resealable medication port. When additive is used, verify tonicity prior to parenteral administration. Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solution is recommended to be administered through a large central vein, for rapid dilution of the hyperosmotic solution.

For further information on the product with additives, please see sections 6.2, 6.3 and 6.6.

4.3 Contraindications

The solution is contraindicated in patients presenting with:

- Known hypersensitivity to the product
- Extracellular hyperhydration or hypervolaemia

- Fluid and sodium retention
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated cardiac failure
- Hyponatraemia or hypochloraemia
- General oedema and ascitic cirrhosis
- Clinically significant hyperglycaemia.

The solution is also contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma or hyperlactataemia.

Paediatric Population
This product should not be used in children except in paediatric specialist settings (such as renal, hepatic and cardiac units high dependency units and intensive care units) under expert medical supervision.

4.4 Special warnings and precautions for use

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).
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 metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia
The infusion of solutions with sodium concentrations <0.9% may result in hyponatraemia. Close clinical monitoring may be warranted.
Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.
Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.
Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia

Sodium retention, fluid overload and oedema
Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be used with particular caution, in:

- Patients with conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as
    - Primary hyperaldosteronism,
    - Secondary hyperaldosteronism associated with, for example,
        - hypertension,
        - congestive heart failure,
        - liver disease (including cirrhosis),
        - renal disease (including renal artery stenosis, nephrosclerosis)
    - Pre-eclampsia.
- Patients taking medications that may increase the risk of sodium and fluid retention, such as corticosteroids

Hypokalaemia
The infusion of Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution may result in hypokalaemia. This medicine should be used with particular caution in patients with or at risk for hypokalemia. Close clinical monitoring may be warranted in, for example:

- persons with metabolic alkalosis
- persons with thyrotoxic periodic paralysis, administration of intravenous glucose has been associated in aggravating hypokalaemia
- persons with increased gastrointestinal losses (e.g., diarrhea, vomiting)
- prolonged low potassium diet
- persons with primary hyperaldosteronism
- patients treated with medications that increase the risk of hypokalaemia (e.g. diuretics, beta-2 agonist, or insulin)

Hypo- and hyperosmolality, serum electrolytes and water imbalance

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution can cause:

- Hypo-osmolality
- Hyperosmolality, osmotic diuresis and dehydration
- Electrolyte disturbances such as
    - hyponatraemia (see above),
    - hypokalaemia (see above),
    - hypophosphataemia,
    - hypomagnesaemia,
- Overhydration/hypervolaemia and, for example, congested states, including central (e.g., pulmonary congestion) and peripheral oedema.

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.

Hyperglycaemia
Rapid administration of glucose solutions may produce substantial hyperglycaemia and a hyperosmolar syndrome. In order to avoid hyperglycaemia the infusion rate should not exceed the patient's ability to utilize glucose.

To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Intravenous glucose should be administered with caution in patients with, for example:

- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma or shock),
- severe malnutrition (risk of precipitating a refeeding syndrome, see below),
- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic
- acidosis due to impaired oxidative metabolism of pyruvate),
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load

Other groups of patients in whom Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be used with caution include:

- patients with ischemic stroke. hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.
- patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma). Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- Newborns (see Paediatric glycaemia-related issues).

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

Hypersensitivity Reactions

- Hypersensitivity/infusion reactions, including anaphylaxis, have been reported (see section 4.8).
- Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.
- Solutions containing glucose should be used with caution in patients with known allergy to corn or corn products

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent these complications.

Severe renal impairment

Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should be administered with particular caution to patients at risk of (severe) renal impairment. In such patients, administration may result in sodium retention and/or fluid overload.

Paediatric use

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

Paediatric Population

Intravenous fluid therapy should be closely monitored in the paediatric populations as they may have impaired ability to regulate fluids and electrolytes. Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.

Paediatric glycaemia-related issues

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. Close monitoring during treatment with intravenous glucose solutions is needed to ensure adequate glycaemic control, in order to avoid potential long term adverse effects.

Hypoglycaemia in the newborn can cause, e.g.,

- prolonged seizures,
- coma and
- cerebral injury.

Hyperglycaemia has been associated with

- cerebral injury, including intraventricular haemorrhage,
- late onset bacterial and fungal infection,
- retinopathy of prematurity,
- necrotizing enterocolitis,
- increased oxygen requirements,
- prolonged length of hospital stay and
- death.

Paediatric hyponatraemia-related issues

- Children (including neonates and older children) are at increased risk of developing hyponatraemia as well as for developing hyponatraemic encephalopathy.
- 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 edema and death; therefore, acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.
- Plasma electrolyte concentrations should be closely monitored in the paediatric population.

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

Blood
Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

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

4.5 Interaction with other medicinal products and other forms of interactions

No studies have been conducted by Baxter.
Both the glycaemic and effects on water and electrolyte balance should be taken into account when administering Sodium Chloride 0.18% w/v and Glucose 4% w/v solution to patients treated with other substances that affect glycaemic control or fluid and/or electrolyte balance.
Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.
Caution is advised in patients treated with

- lithium. Renal sodium and lithium clearance may be increased during administration and can result in decreased lithium levels.
- corticosteroids, which are associated with the retention of sodium and water (with oedema and hypertension).
- diuretics, beta-2 agonist, or insulin, whom increase the risk of hypokalemia
- certain antiepileptic and psychotropic medications that increase the risk of hyponatraemia.

4.6 Fertility, pregnancy and lactation

Pregnancy
Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia and metabolic acidosis as well as rebound neonatal hypoglycaemia due to foetal insulin production.
Sodium Chloride 0.18 % w/v and Glucose 4% w/v solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

Fertility
There is no information on the effects of Sodium Chloride 0.18% w/v and Glucose 4% w/v solution on fertility

Lactation
Sodium Chloride 0.18% w/v and Glucose 4% w/v solution can be used during breast-feeding. The potential risks and benefits for each specific patient should be carefully considered before administration.

4.7 Effects on ability to drive and use machines

There is no information on the effects of Sodium Chloride 0.18 % w/v and Glucose 4% w/v solution on the ability to operate an automobile or other heavy machinery

4.8 Undesirable effects

The following adverse reactions have been reported in post-marketing experience, listed by MedDRA System Organ Class (SOC), then where feasible, by Preferred Term in order of severity.
Frequencies cannot be estimated from the available data as all listed adverse reactions are based on spontaneous reporting

System Organ Class	Adverse reactions (Preferred terms)	Frequency
Immune system disorders	anaphylactic reaction,	Not known
	hypersensitivity	
Metabolism and nutrition disorders	hyponatraemia,	Not known
	hyperglycaemia,	
	hospital acquired hyponatraemia**	
Nervous system disorders	hyponatraemic encephalopathy**	Not known
Vascular disorders	phlebitis	Not known
Skin and subcutaneous tissue disorders	rash	Not known
	pruritus	
General disorders and administration site conditions	Injection site reactions including:	Not known
	pyrexia	
	chills	
	infusion site pain	
	infusion site vesicles	

*Potential manifestation in patients with allergy to corn, see section 4.4
** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Adverse reactions may be associated to the medicinal product(s) added to the solution; the nature of the additive will determine the likelihood of any other adverse reactions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Excess administration of Sodium Chloride 0.18 % w/v and Glucose 4 % w/v solution can cause:

- Hyperglycaemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycaemia and severe dilutional hyponatraemia, and their complications, can be fatal.
- Hyponatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death).
- Fluid overload (which can lead to central and/or peripheral oedema).
- See also sections 4.4 and 4.8

When assessing an overdose, any additives in the solution must also be considered.
Clinically significant overdose of Sodium Chloride 0.18% w/v and Glucose 4% w/v solution may therefore, constitute a medical emergency.
Interventions include discontinuation of administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes with Carbohydrates

ATC code: B05BB02.
0.18% w/v Sodium Chloride and 4.0% w/v Glucose is an isotonicsolution of sodium chloride and glucose.

The pharmacodynamic properties of this solution are those of its components (glucose, sodium and chloride).

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and also in its renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Glucose is the principal source of energy in cellular metabolism.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of this solution are those of its components (glucose, sodium, and chloride).
After injection of radiosodium (^{24}Na), the half life is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurones; it is very slow in the bone. Sodium is predominantly excreted by the kidney, but (as described earlier) there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

5.3 Preclinical safety data

The preclinical safety assessment of 0.18% w/v Sodium Chloride and 4.0% w/v Glucose solution for infusion in animals is not relevant as sodium chloride and glucose are physiological constituents of the body and are covered by appropriate pharmacopoeial references.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Incompatibility of the medicinal product to be added with the solution in the Viaflo container must be assessed before addition.
In the absence of compatibility studies, this solution must not be mixed with other medicinal products.
The Instructions for Use of the medicinal product to be added must be consulted.
Before adding a drug, verify it is soluble and stable in water at the pH of Sodium Chloride 0.18% w/v and Glucose 4% w/v solution (see section 3).
As guidance, the following medications are incompatible with the Sodium Chloride 18 % w/v & Glucose 4% w/v solution (non-exhaustive listing):
- Ampicillin sodium
- Mitomycin
- Erythromycin lactobionate
- Human insulin

Those additives known to be incompatible should not be used.
Because of the presence of glucose, Sodium chloride 0.18% w/v and Glucose 4% w/v solution should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

6.3 Shelf life

Unopened: 3 years. Once opened, use immediately. Discard any unused portion.

In-use shelf-life (additives)
Chemical and physical stability of any additive medication at the pH of the Sodium Chloride 0.18% and Glucose 4% solution in the Viaflo container should be established prior to use. From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The bags, known as Viaflo, are composed of polyolefin/polyamide co-extruded plastic (PL 2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene.
Bag sizes: 500 and 1000ml (not all pack sizes may be marketed).
Outer carton contents: - 20 bags of 500ml
- 10 bags of 1000ml

6.6 Special precautions for disposal and other handling

Use only if the solution is clear, without visible particles and if the container is undamaged.

Administer immediately following the insertion of infusion set.

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

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 the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique.

The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before administration or during administration through the resealable medication port.
When additive is used, verify tonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately after preparation unless preparation has taken place in controlled and validated aseptic conditions.

Adding other medications or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of an adverse reaction, infusion must be stopped immediately.

Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.

1. Opening
a. Remove the Viaflo container from the overpouch just before use.
b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be broken.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration
Use sterile material for preparation and administration.

a. Suspend container from eyelet support.
b. Remove plastic protector from outlet port at bottom of container:
grip the small wing on the neck of the port with one hand,
grip the large wing on the cap with the other hand and twist,
the cap will pop off.
c. Use an aseptic method to set up the infusion.
Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications
Warning: Additives may be incompatible

To add medication before administration

a. Disinfect medication site.
b. Using syringe with 19 gauge (1.10mm) to 22 gauge (0.7mm) needle, puncture resealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration
a. Close clamp on the set.
b. Disinfect medication site.
c. Using syringe with 19 gauge (1.l0mm) to 22 gauge (0.7mm), puncture resealable medication port and inject.
d. Remove container from IV pole and/or tum to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

Baxter Holding B.V.
Kobaltweg 49
3542CE Utrecht
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA2299/008/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 24th August 2007
Date of Last Renewal: 24th August 2012.

10 DATE OF REVISION OF THE TEXT

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