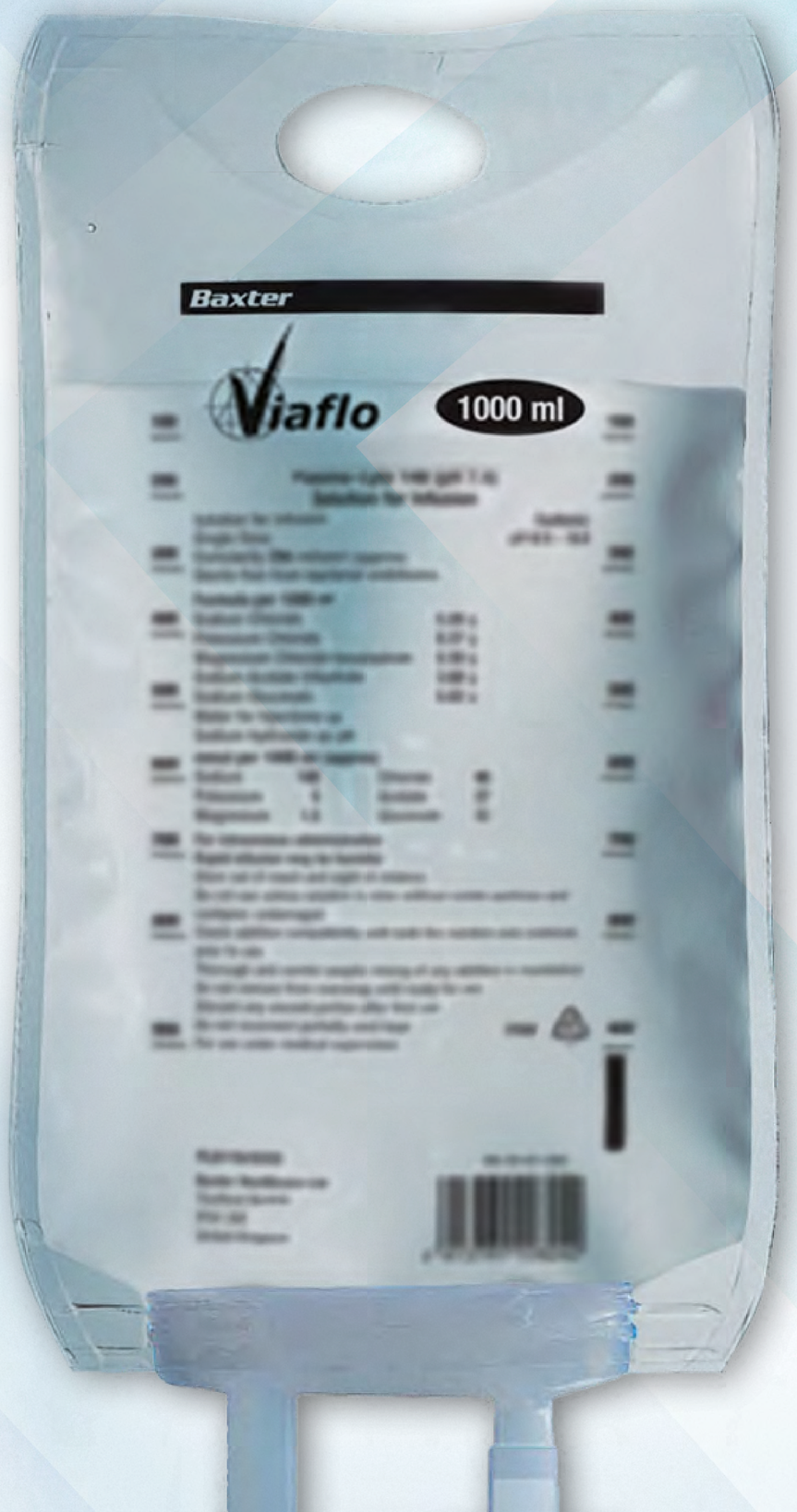
Baxter

Viaflo

CONTAINER SYSTEM

Viaflo

Optimize standards of care in IV therapy delivery



Viaflo — an optimized, closed-system IV bag to help support your daily practice

Viaflo is designed to be easy to use, versatile and efficient

Efficiency:

- Minimal air volume
- High admixture volume
- Low residual volume

Ease of use:

- Large, pre-cut hanger
- Fully flexible bag
- Dedicated administration port with twist-off protector
- Dedicated, rigid medication port

Versatility:

- Broad range of:
  - Solutions
  - Volumes
  - Drug compatibility data
- Works with **Vial-Mate** to aid reconstitution

Offering:

- Integrated film printing (no separate label) with dedicated label design and barcode identification help prevent medication errors
- Non DEHP, PVC free, latex free and aluminium free
- Closed-system design helps reduce the risk of contact contamination
- Dripless accessory component

DEHP, Di-(2-ethylhexyl)-phthalate; PVC, Polyvinyl Chloride.

Healthcare-associated bloodstream infections: an IV therapy challenge

It is estimated that each year, hundreds of million of patients around the world could be affected by Hospital acquired infections.[10]

Healthcare-associated infection incidence[2]

Healthcare-related infections are associated with significant mortality and increased costs.[1,3]

Healthcare-associated bloodstream infections: an IV therapy challenge

It is estimated that each year, hundreds of million of patients around the world could be affected by hospital acquired infections.[10]

Annual mortality rates attributable to healthcare-associated infections

England[1]

>5k

Mexico[1]

32
deaths
per 100,000 inhabitants

US[3]

100k
(4th leading cause of death)

Healthcare-related infections are associated with significant mortality and increased costs.[1,3]

Healthcare-associated bloodstream infections: an IV therapy challenge

It is estimated that each year, hundreds of million of patients around the world could be affected by hospital acquired infections.[10]

Cost of catheter-related bloodstream infections (CR-BSI)[4]

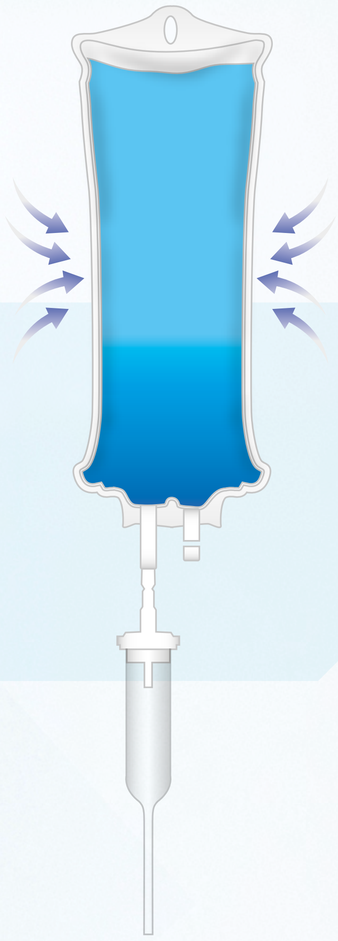
Country	CR-BSI cases/year	Additional length of stay per CR-BSI episode (days)	Additional costs per CR-BSI episode (€)
France	14,400	9.5–14	7,730–11,380
Germany	8,400	4.8–7.2	4,200
Italy	8,500	12.7	13,030
UK	8,940	1.9–4	4,392–9,251

Healthcare-related infections are associated with significant mortality and increased costs.[1,3]

Closed-system design helps minimize bloodstream infection risk[5]

Viaflo is a closed, flexible, fully collapsible container.

Unlike open systems, **Viaflo** doesn't need to be vented to empty completely. This prevents introduction of external contaminants.[6]



Collapsible Closed System

Semi-Rigid Open System

In a meta-analysis by Maki DG *et al*, central line-associated bloodstream infections were reduced by 67% when switching from an open to a closed system.[5]

Closed-system design helps minimize bloodstream infection risk[5]

Switching from an open to a closed system can help reduce all-cause ICU mortality by 23%.[5]

CLA-BSI* by Microorganism

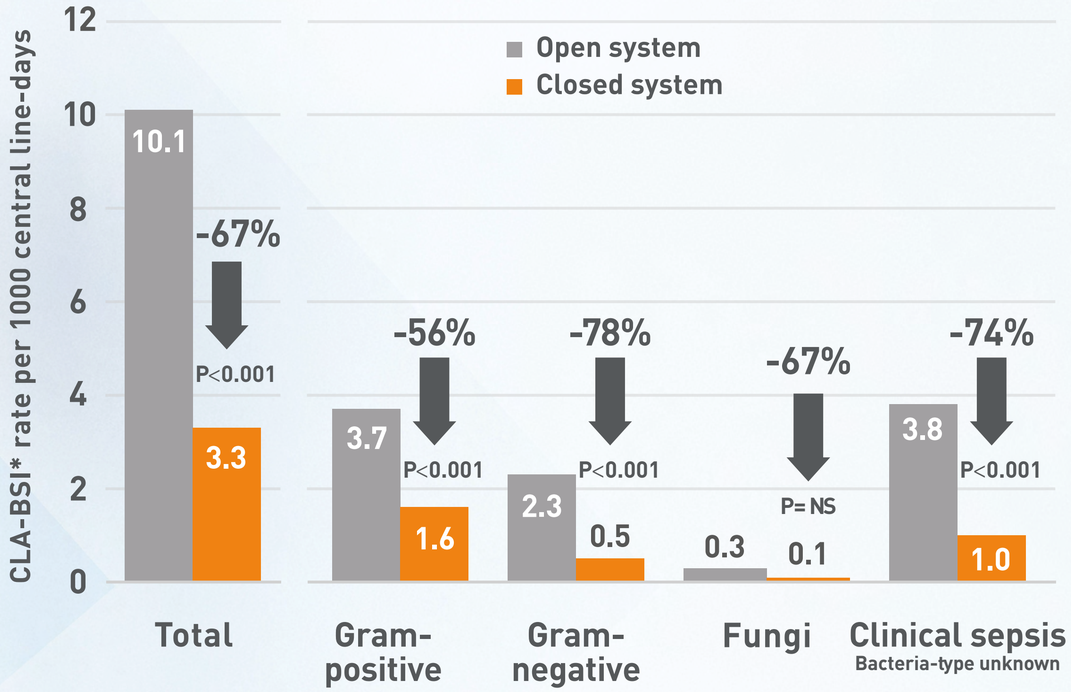


Figure adapted from Maki DG *et al*. 2011.[5]

*CLA-BSI: central line–associated bloodstream infection defined in this study as laboratory-confirmed bloodstream infection and clinical primary nosocomial sepsis.

Closed-system design helps minimize bloodstream infection risk[5]

Switching from an open to a closed system can help reduce all-cause ICU mortality by 23%.[5]

ICU mortality rate

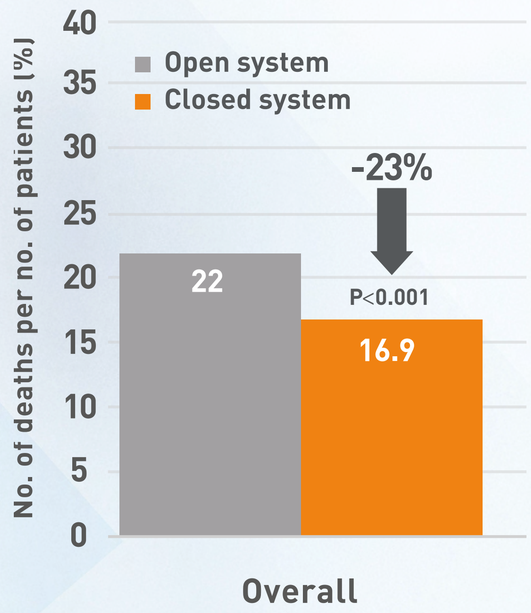


Figure adapted from Maki DG *et al.* 2011.[5]

Closed-system design helps minimize bloodstream infection risk[5]

Switching from an open to a closed system can help reduce all-cause ICU mortality by 23%.[5]

CLA-BSI* by country

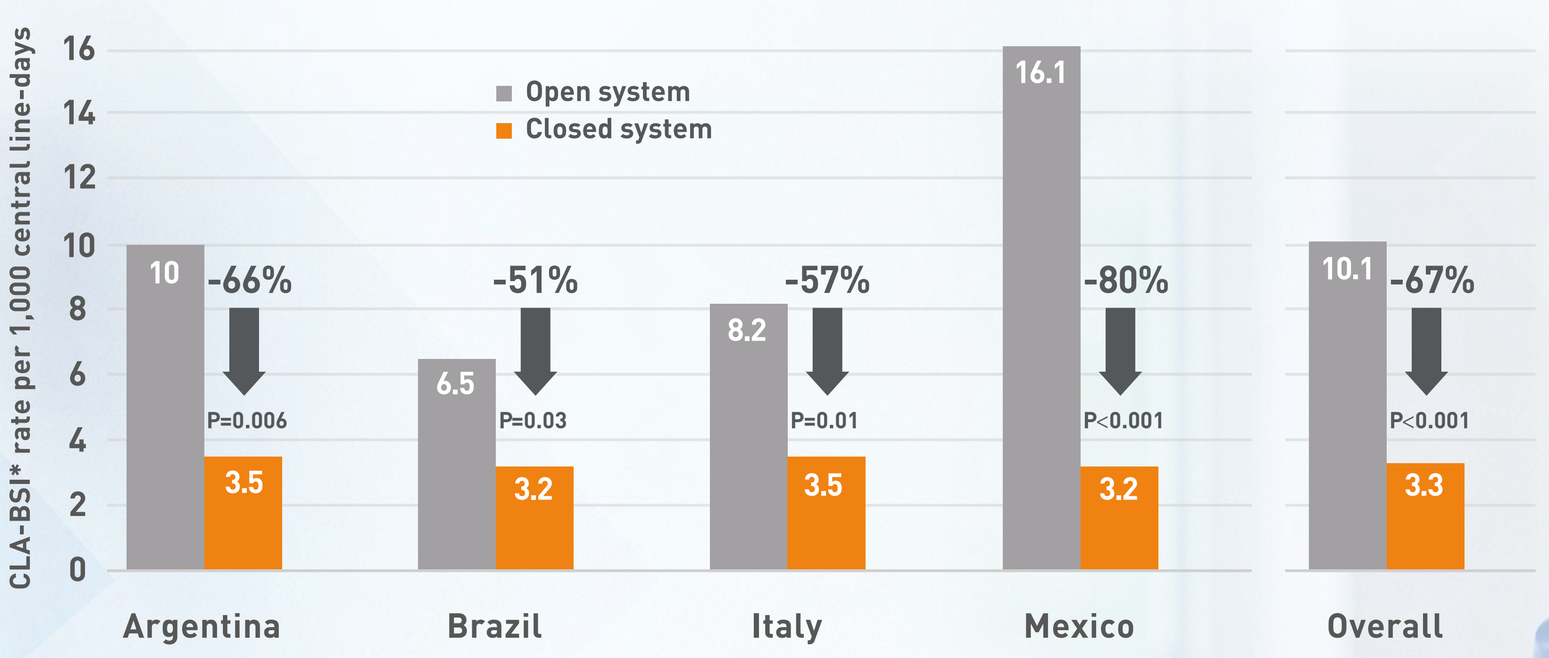


Figure adapted from Maki DG *et al*. 2011.[5]

*CLA-BSI: central line–associated bloodstream infection defined in this study as laboratory-confirmed bloodstream infection and clinical primary nosocomial sepsis.

A multi-layered, overwrapped design built on experience and cutting-edge technology

Viaflo has a multi-layer design. **Viaflo's** inner layer allows for high compatibility with administered drugs, with less leaching and adsorption.

Viaflo is made from three co-extruded layers

External polypropylene layer
water vapour barrier

Centre polyamide layer
mechanical strength and gas barrier

Internal polyethylene layer
high compatibility

A multi-layered, overwrapped design built on experience and cutting-edge technology

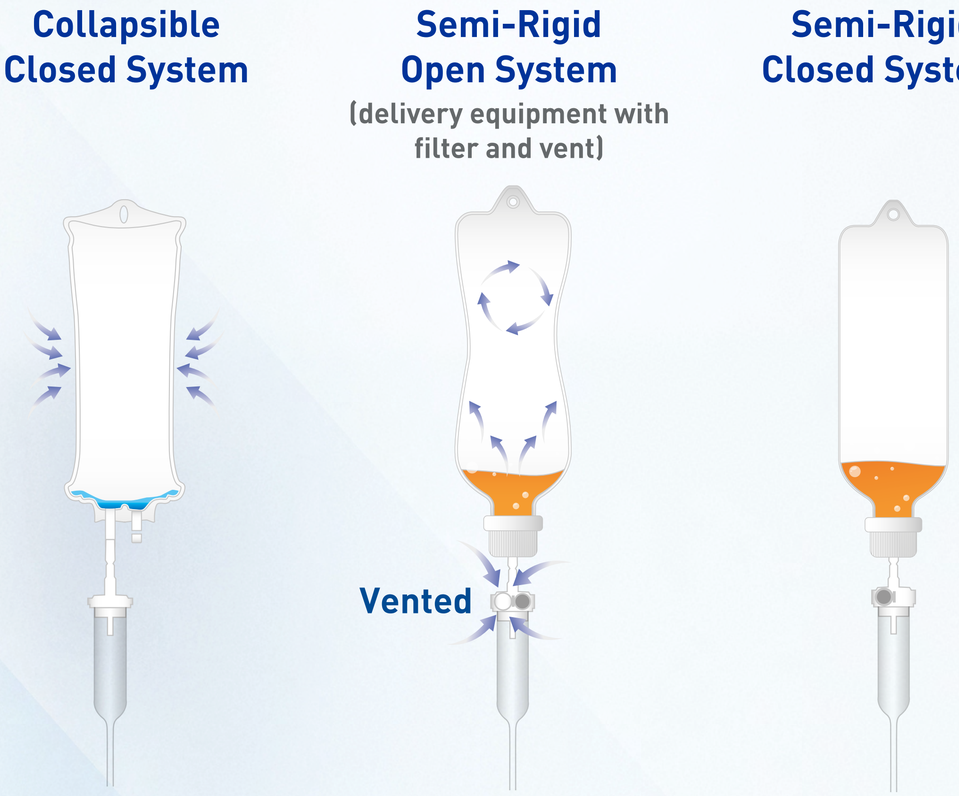
Viaflo has a multi-layer design. **Viaflo's** inner layer allows for high compatibility with administered drugs, with less leaching and adsorption.

Viaflo is overwrapped for additional protection

- The **Viaflo** bag is sterilized within its overwrap
- The overwrap does not stick to the primary bag, making it easy and fast to open

Viaflo is a fully collapsible bag

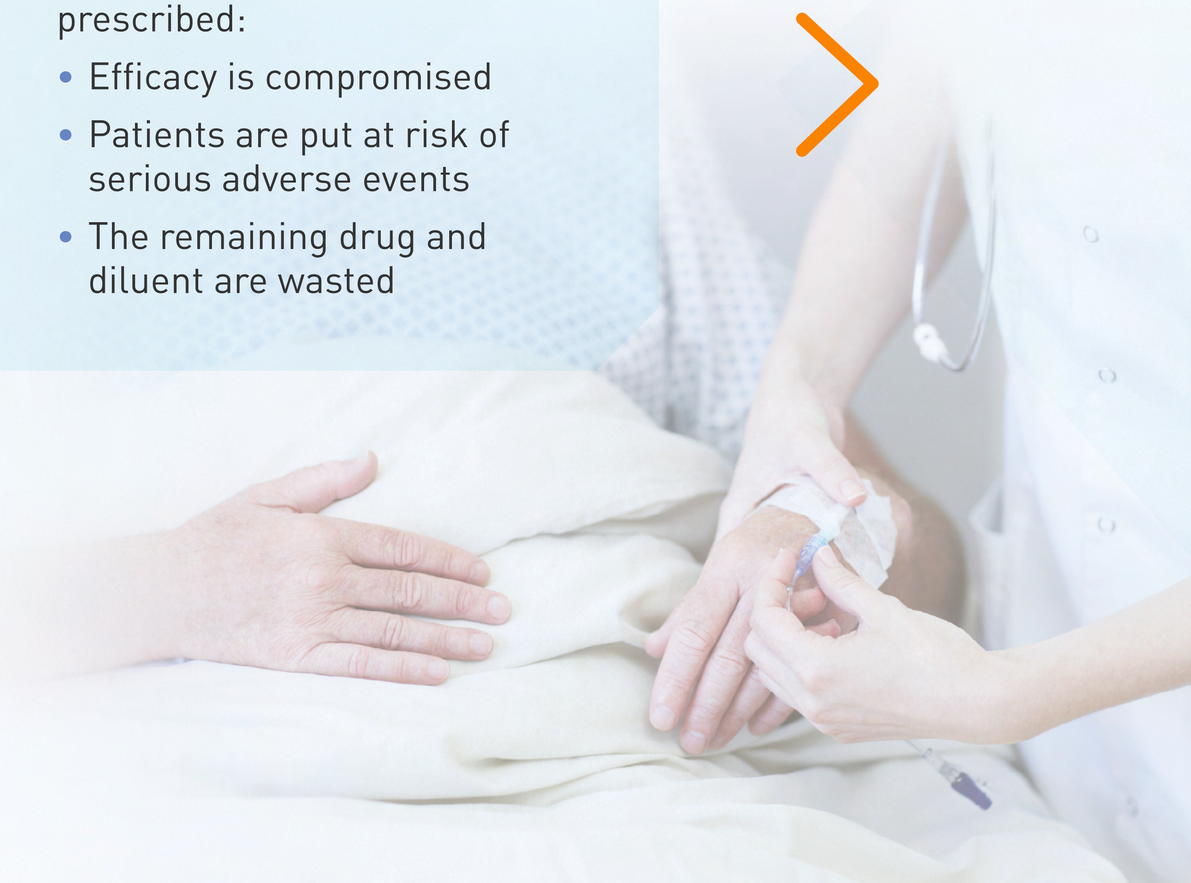
Containers, used as a closed system, should have a minimal residual volume after the drug solution has been completely delivered, to help ensure the patient receives the intended prescribed dose.



When the amount of medication given differs from the amount prescribed:

- Efficacy is compromised
- Patients are put at risk of serious adverse events
- The remaining drug and diluent are wasted

Viaflo, a fully collapsible bag, leaves lower residual volumes than semi-rigid systems to help ensure your patient receives the added medication[8,9]



Viaflo is a fully collapsible bag

Containers, used as a closed system, should have a minimal residual volume after the drug solution has been completely delivered, to help ensure the patient receives the intended prescribed dose.

When used as a closed system, the mean residual volume:[8]

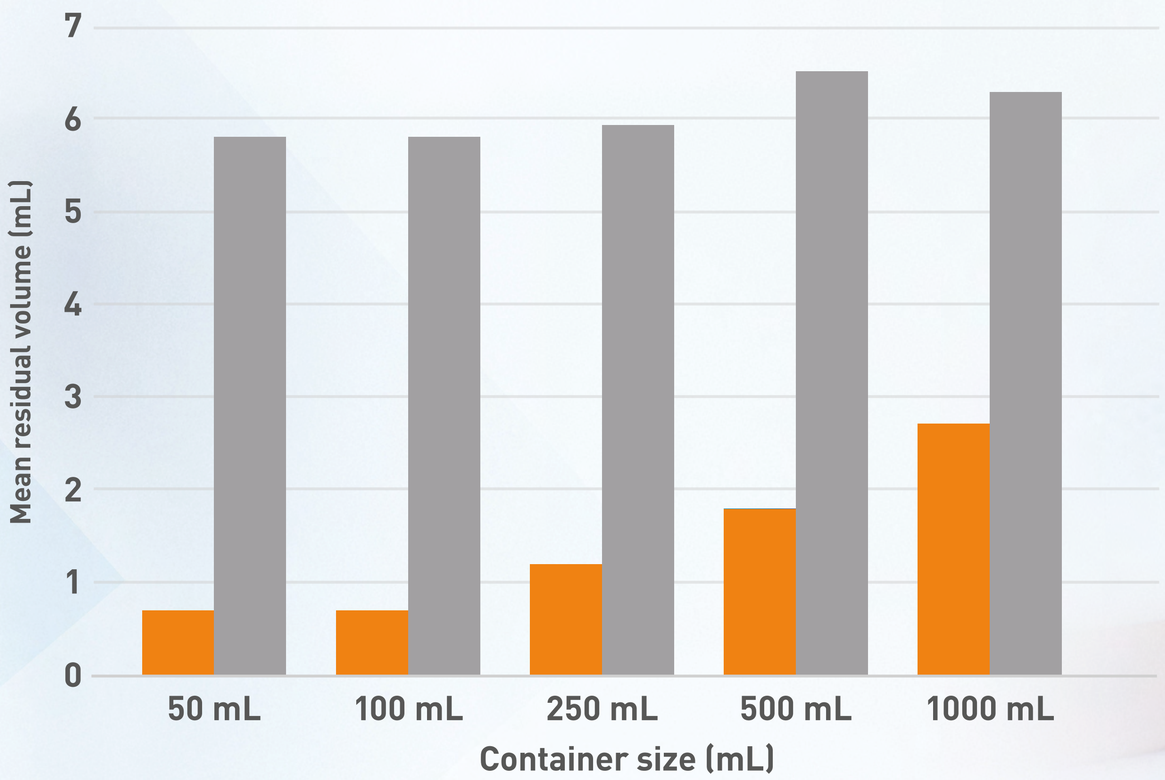
Is only 1.4% in collapsible bags

Could go up to 11.7% in semi-rigid containers

Viaflo is a fully collapsible bag

Containers, used as a closed system, should have a minimal residual volume after the drug solution has been completely delivered, to help ensure the patient receives the intended prescribed dose.

Results of an observational study comparing collapsible vs. semi-rigid containers[8]



Graph adapted from Gabay M, von Martius K. 2008.[8]

Types of infusion systems

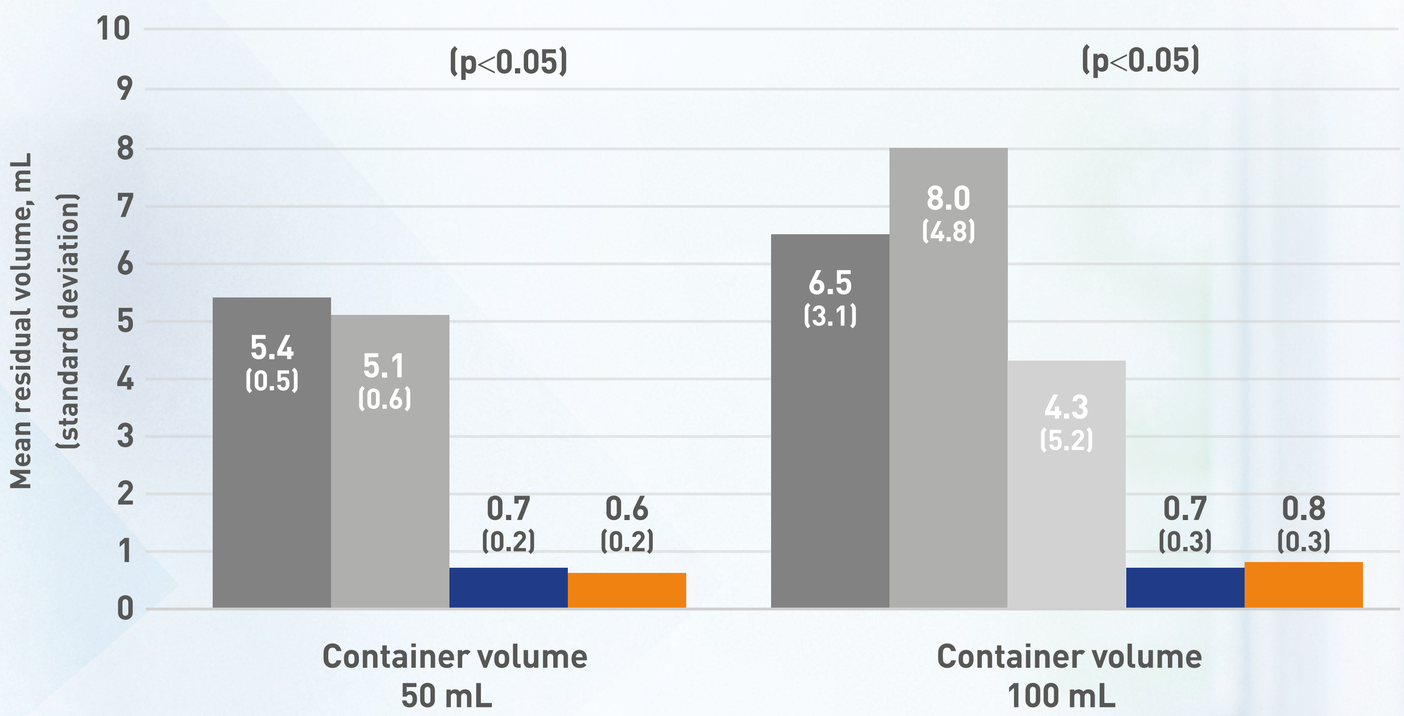
Collapsible
Closed System

Semi-Rigid
Open System
(vented container)

Viaflo is a fully collapsible bag

Containers, used as a closed system, should have a minimal residual volume after the drug solution has been completely delivered, to help ensure the patient receives the intended prescribed dose.

Mean residual volume and standard deviation under closed vent conditions[9]



Graph adapted from Lannoy D *et al*. 2012.[9]

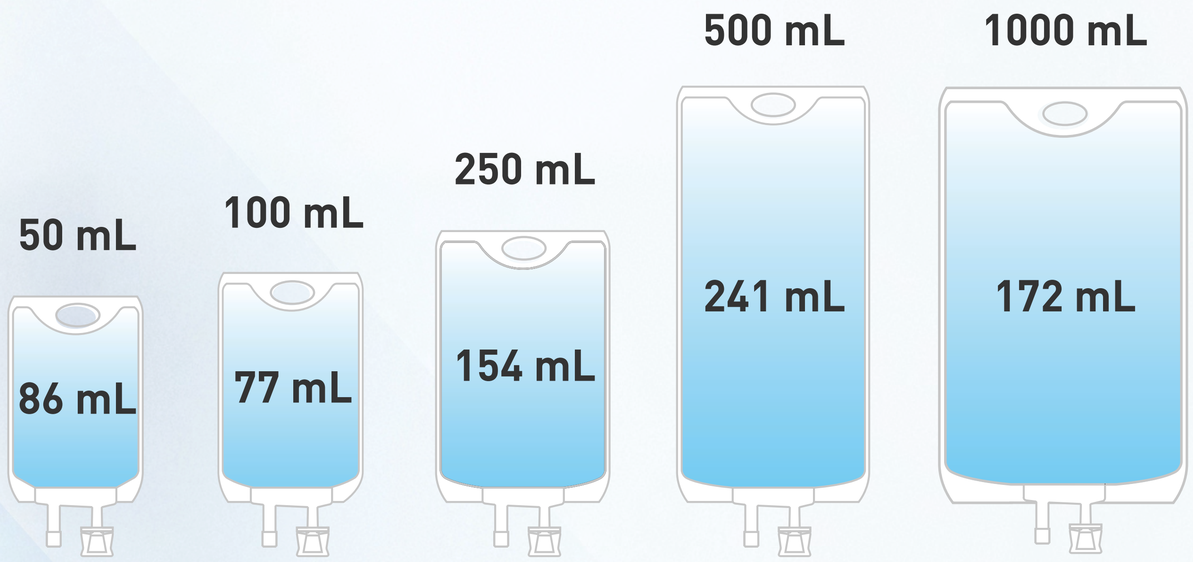
Viaflo has a low residual volume

Average residual volume

Average measures

Viaflo — making high drug admixture volumes easy

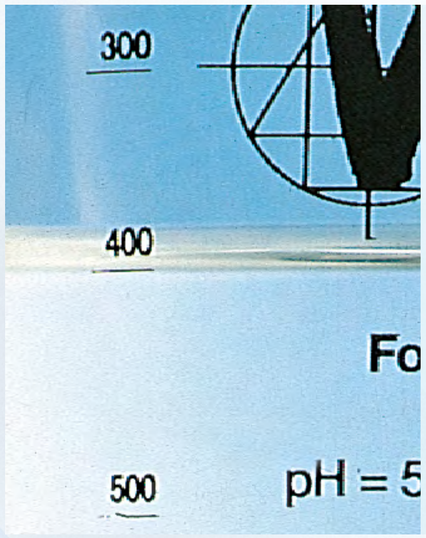
Maximum admixture volume



Viaflo allows high drug admixture volumes, reducing the need to remove solution from the **Viaflo** container. Eliminating this extra step could mean:[7]

- Less manipulation of the bag is required
- Lower risk of contact contamination
- Lower risk of needlestick injury

Viaflo helps prevent medication administration errors



The Viaflo bag collapses without wrinkling during administration

This enables easy readability of the administered volume (indicative).

Tamper evidence

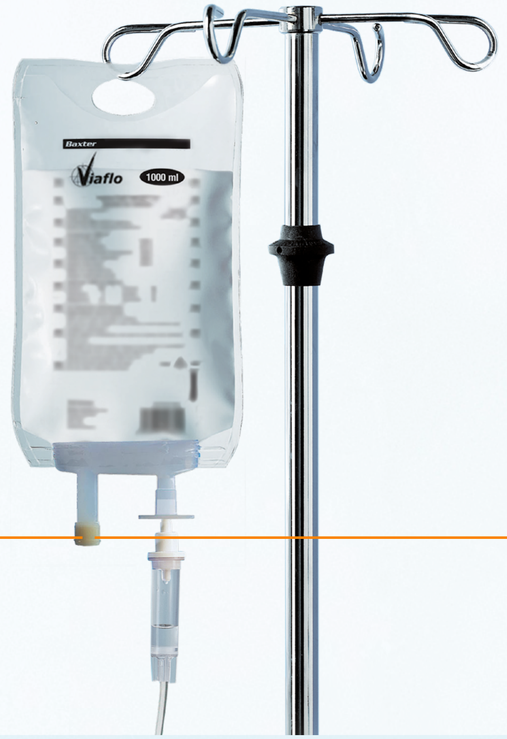
The add-a-cap tamper device helps avoid accidental addition of non-intentional drugs.

Viaflo's design helps to reduce risk of needlestick injury[7]

Viaflo has several design features for ease of use and helps to reduce risk of needlestick injury.

Rigid port:

- Easy to grip
- Ensure not to fold while inserting the needle



Port length:

- Aligned with average needle length

Appropriate distance between the ports:

- To support easy drug admixture

Viaflo incorporates Baxter's advanced reconstitution systems[7]

Baxter's transfer device and Vial-Mate:[7]

- Provide a closed-system concept, **helping to reduce the risk of microbial contamination** during reconstitution
- **Minimize risk of** needlestick injury
- Are **specifically designed and validated** for use with **Viaflo**

Baxter's transfer device

Vial-Mate, based on innovative technology, offers additional benefits of:[7]

- **Delayed activation and drug reconstitution just before use**
  - Especially important when reconstituting drugs with a short stability
- **Reduced risk of medication errors**
  - The drug vial stays attached to the bag for easy drug identification and reduced risk of tampering

Vial-Mate

Vial-Mate is only available in certain countries.

Viaflo is pressure-cuff compatible[7] when required in critical situations

Pressure-cuff compatible

- Universal and easy to use, enabling consistent practice throughout your hospital[7]
- Both 500 mL and 1000 mL **Viaflo** bag sizes are compatible with 1000 mL size pressure-cuff

Viaflo size	Pressure-cuff size	< 72 hours at 350 mmHg
500 mL	1000 mL	no leaks
1000 mL	1000 mL	no leaks

Resistance to pressure

- The **Viaflo** bag can be used with a pressure cuff at a pressure of 350 mmHg for 72 hours[7]

Please ensure compatibility of the Viaflo container with the pressure cuff used. The pressure cuff should completely cover the Viaflo container.

Viaflo can be warmed for patients to help prevent hypothermia

Prior to infusing IV solutions in patients to help prevent hypothermia, you can heat **Viaflo** in a warming cabinet.

Storage of Viaflo solutions in a warming cabinet:

Although Baxter recommends minimal exposure of any pharmaceutical product to heat, **Viaflo** solutions can be warmed in their over pouch using a warming cabinet to a temperature not exceeding 40°C.[7]

- **Viaflo 500 mL format for a period of 7 weeks**
- **Viaflo 1000 mL format for a period of 14 weeks**

The **Viaflo** containers may continue to be used until the labelled expiration date, provided they are not warmed more than once and are identified as having been warmed.

For more detailed information, please ask your local Baxter representative.

Practical tips for **Viaflo** storage and use

Viaflo storage

The storage carton is designed with a dispenser feature for easy access to products.

Opening the overwrap and removing the Viaflo bag

1. **Apply aseptic technique.** The overwrap has a slit near each top corner. Hold the bag vertically by the overwrap. Grasp the top seal of the overwrap close to a slit.

2. Tear the overwrap from the slit downwards in a smooth movement.

3. There is minimal sticking of the primary bag to the overwrap, allowing easy removal.

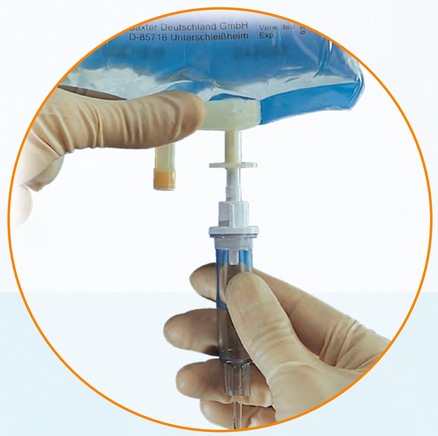
Practical tips for **Viaflo** storage and use

Viaflo storage

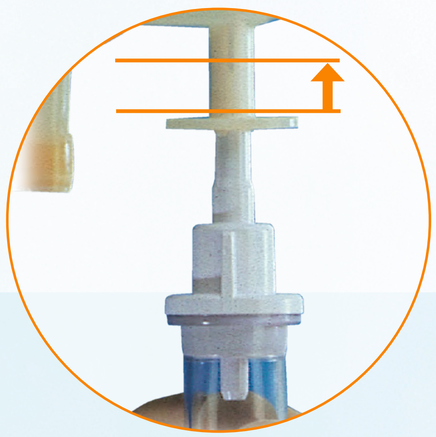
The storage carton is designed with a dispenser feature for easy access to products.

Safe spike connection

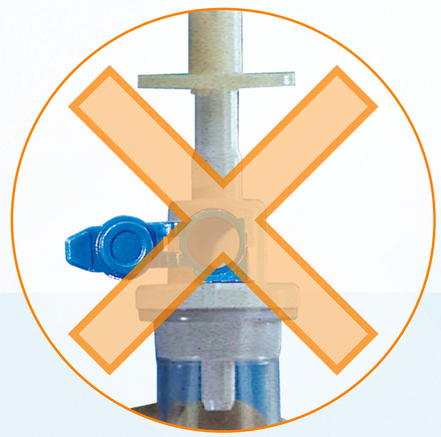
1. **Apply aseptic technique.** Remove the spike protector cap from the set and close its roller clamp. Twist off the protector cap from the administration port of the bag.



2. Hold the base of the port system and insert the spike. A slight resistance should be felt as the port membrane is broken.



3. Use a twisting motion during insertion. Insert the spike until the raised section of the spike is level with the port. Do not fold the bag during insertion to avoid bag piercing.



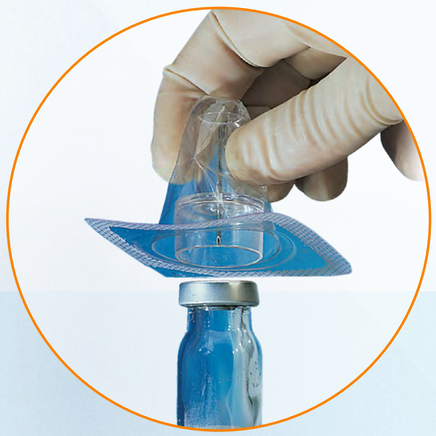
4. Closed-system administration. If using a set with a vent, do not open the vent as this is not required with the **Viaflo** flexible container.

Practical tips for **Viaflo** storage and use

Viaflo storage

The storage carton is designed with a dispenser feature for easy access to products.

Drug reconstitution using Baxter's transfer device



1. Apply aseptic technique. Disinfect the vial stopper and the medication port. Hold the device by the outer packaging, remove the peel pouch at the bottom and push the device onto the top of the drug vial.

2. Push the vial and the reconstitution device up onto the medication port to perforate the injection site membrane.

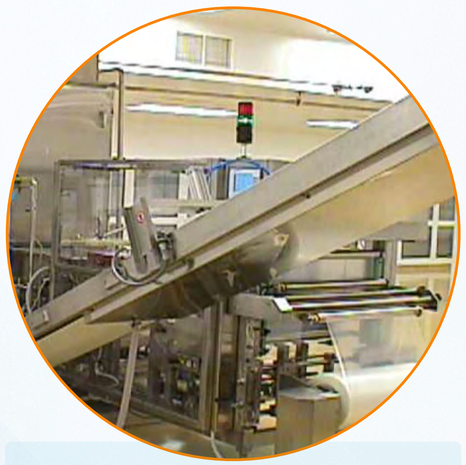
3. Hold the bag with the vial bottom pointing down. Squeeze solution into the vial until ⅓ or ½ full. Shake to reconstitute the drug.

4. Hold the bag with the vial upside down. Squeeze the bag to exchange air into the vial and drain reconstituted drug from the vial into the bag.

Viaflo is produced with quality and efficiency by a trusted manufacturer

Viaflo's high standard is thanks to Baxter's unique, fully-integrated and continuous manufacturing process.

Viaflo high-standard performance is due to the unique, fully-integrated and continuous manufacturing process.



Form-Fill-Seal technology.

Quality and efficiency from start to finish

Our fully-integrated process ensures optimal production and quality control for Viaflo – from multi-layer film manufacturing, to bag production, to overwrapping.

Baxter Belgium Production and Warehouse Center

Baxter — centre of excellence and innovation

Research, innovation and clinical excellence to support patient safety and customer needs

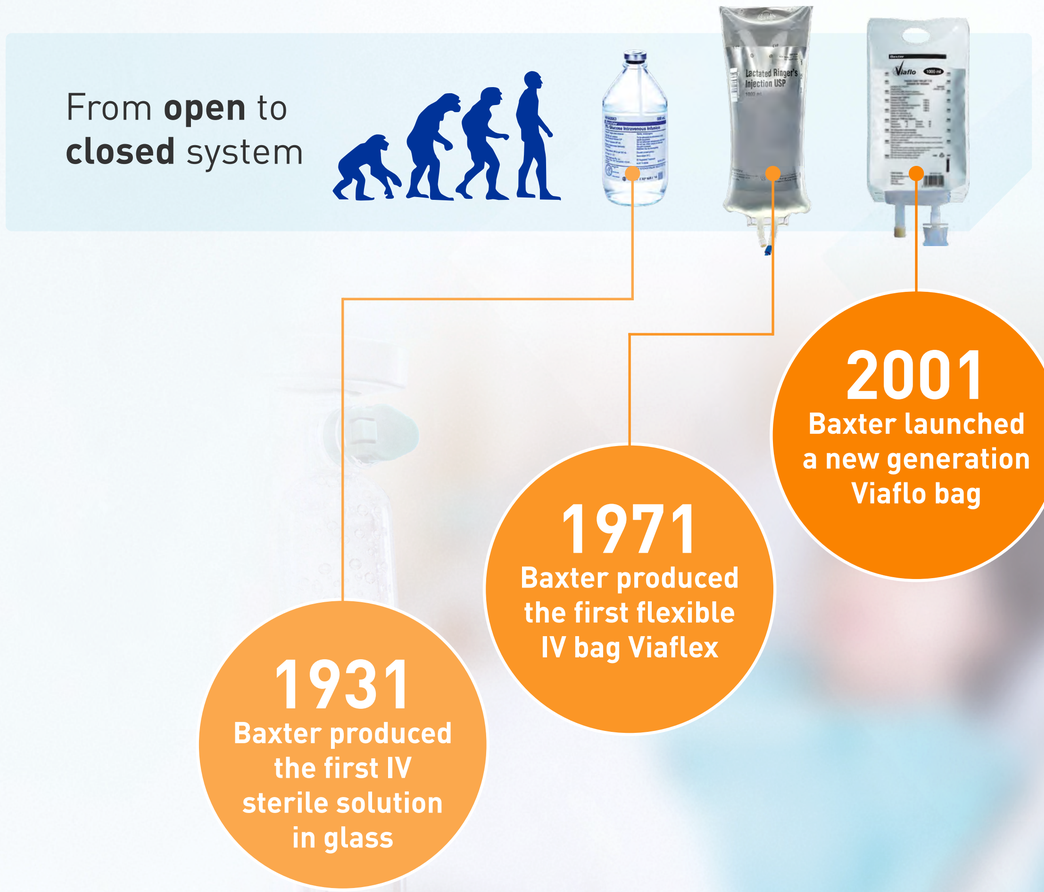
- Not only are Baxter a trusted manufacturer and provider of medical supplies, we have a long heritage of research and technological innovation
- We continuously draw on our experience and growing know-how to create effective products designed with patients in mind

Baxter is a pioneer in clinical research

Baxter's European research and development centre supports international activities and research with:

- A multidisciplinary group of scientists, engineers and technicians
- Strict adherence to internal procedures and external guidelines

The development of **Viaflo's** closed system is just one expression of Baxter's ongoing innovation, growing knowledge and evolving technology:



Baxter — a manufacturer with expertise on drug compatibility

Continuous testing for compatibility and stability

Baxter provides up-to-date compatibility and stability information on a range of drugs:[7]

- Collected since 1971 to support critical decision making and patient safety
- Based on bibliography AND in-house stability testing using well-defined methodology
- Stability studies performed in our international research & development lab, using strict norms and procedures
- Admixed drug stability studies designed to mimic real life conditions

Admixed drug stability information provided on specific request or available from: www.stabforum.com. For more information, please ask your local Baxter representative.

Baxter — a manufacturer with expertise on drug compatibility

Baxter generates stability data using a strict methodology*

- **Analytical method validation**
- **Standard protocol**
- **Molecule tested**
- **Determination of shelf life**

*www.stabforum.com

Baxter — a manufacturer with expertise on drug compatibility

Baxter generates stability data using a strict methodology*

Analytical method validation +

Standard protocol +

Molecule tested +

Determination of shelf life +

Analytical method validation ensures our tests will provide accurate drug stability

*www.stabforum.com

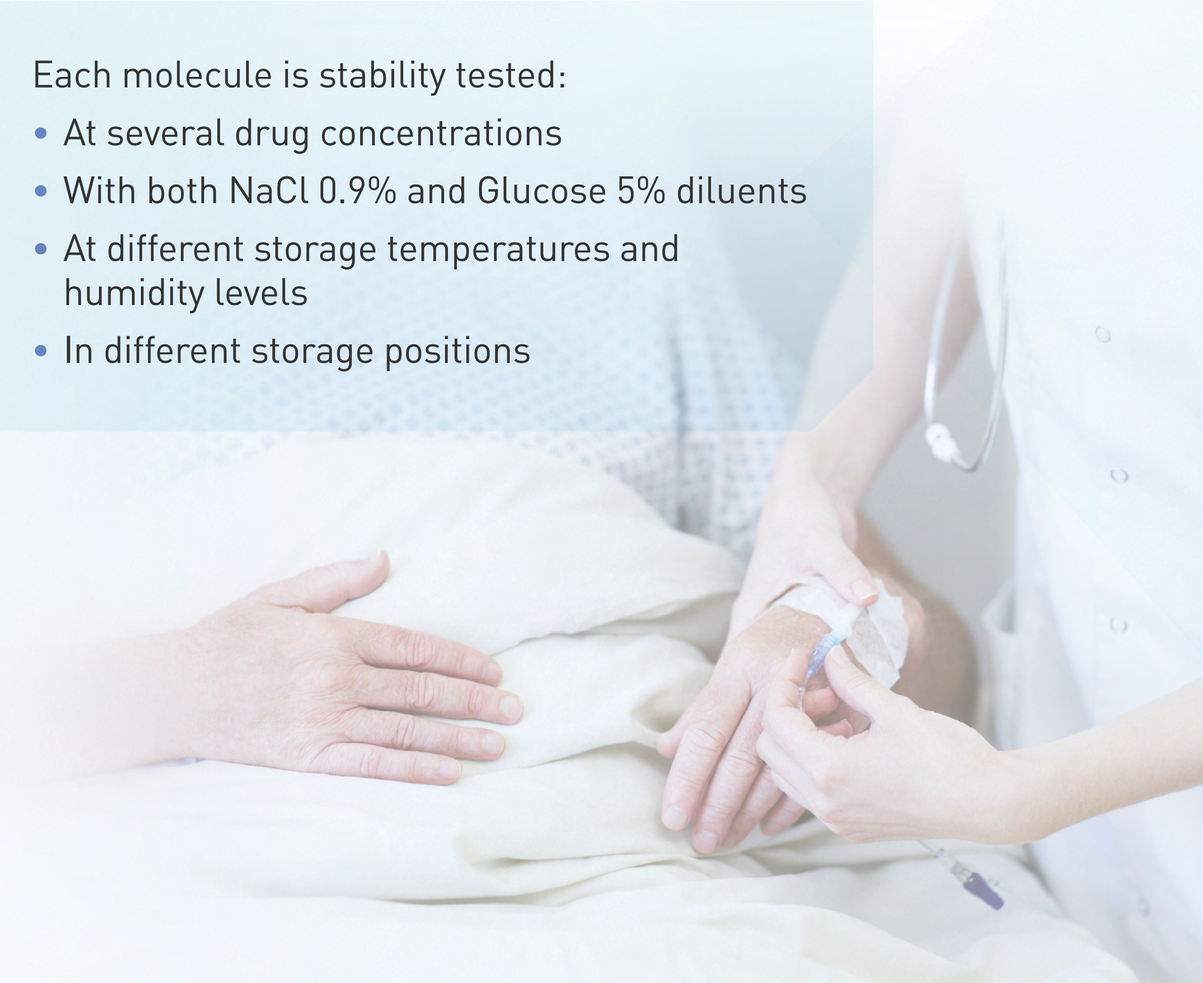
Baxter — a manufacturer with expertise on drug compatibility

Baxter generates stability data using a strict methodology*

- **Analytical method validation**
- **Standard protocol**
- **Molecule tested**
- **Determination of shelf life**

Each molecule is stability tested:

- At several drug concentrations
- With both NaCl 0.9% and Glucose 5% diluents
- At different storage temperatures and humidity levels
- In different storage positions



NaCl, Sodium Chloride.

*www.stabforum.com

Baxter — a manufacturer with expertise on drug compatibility

Baxter generates stability data using a strict methodology*

Analytical method validation +

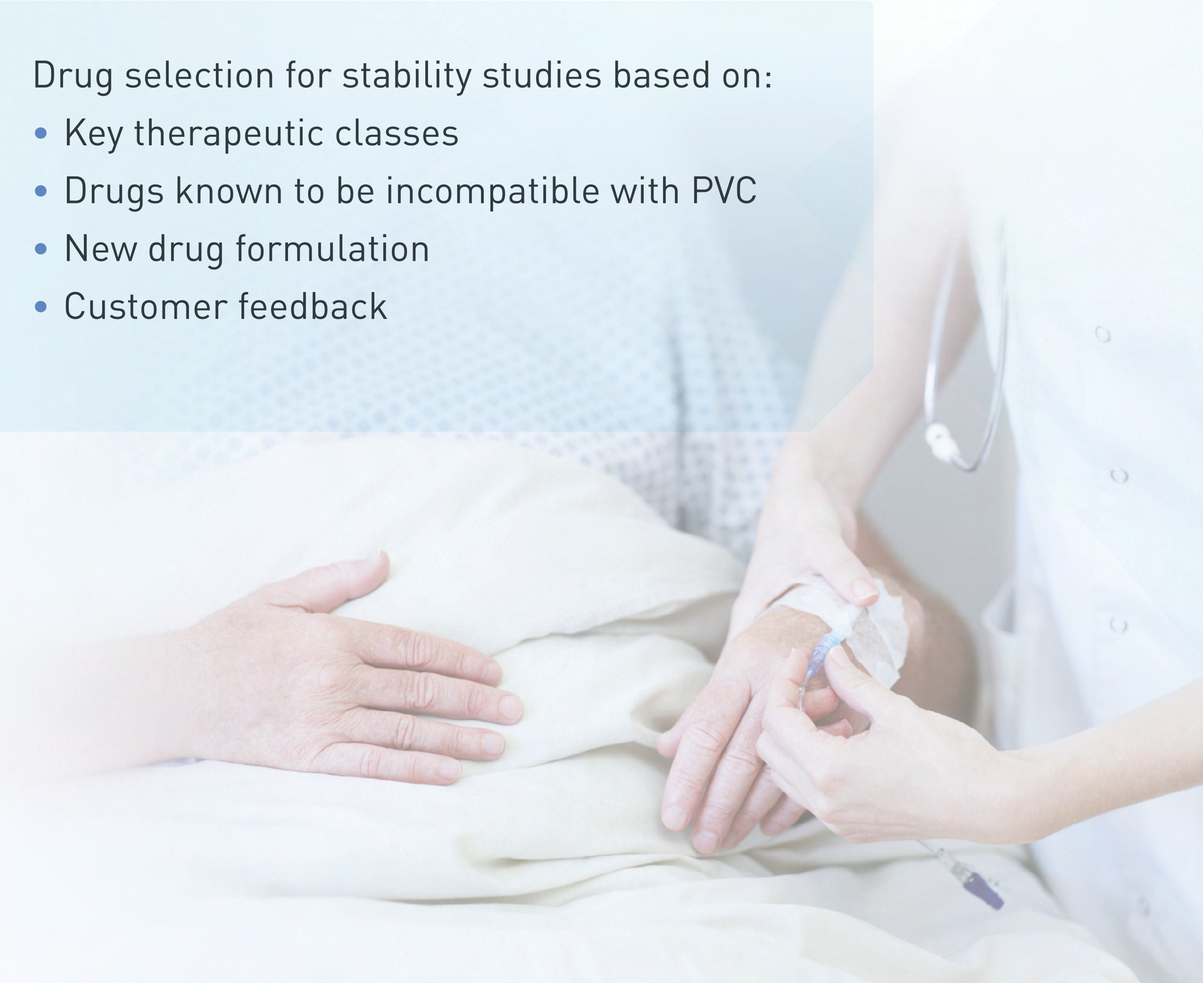
Standard protocol +

Molecule tested +

Determination of shelf life +

Drug selection for stability studies based on:

- Key therapeutic classes
- Drugs known to be incompatible with PVC
- New drug formulation
- Customer feedback



PVC, Polyvinyl Chloride.

*www.stabforum.com

Baxter — a manufacturer with expertise on drug compatibility

Baxter generates stability data using a strict methodology*

Analytical method validation +

Standard protocol +

Molecule tested +

Determination of shelf life +

- Using the highest quality standards (ICH, BP, USP)
- Using a 95% confidence interval
- Based on real testing periods (no extrapolation)

BP, British Pharmacopoeia; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; USP, United States Pharmacopeia.

*www.stabforum.com

Our passion and drive for sustainability shape our products

We recently re-assessed the carbon footprint for **Viaflo** 1000 mL, using a full 'life cycle assessment' to identify the life cycle stages where we can reduce the product's environmental impact.[7]
This work has been independently verified to the ISO 14044 and ISO 14067 standards.

Improved resource efficiency for a reduced carbon footprint[7]

▼33%

Carbon footprint of 1000 mL **Viaflo** reduced by 33% since 2014 due to increased transport efficiency and use of renewable electricity for manufacturing.

ISO, International Organization for Standardization.

Our passion and drive for sustainability shape our products

Renewable electricity for Viaflo

Supporting EU manufacturing and reducing transport distances

Resource efficiencies help make Viaflo a more sustainable product[7]

Facilities committed to continuous environmental improvement

Reduced packaging and waste

Our passion and drive for sustainability shape our products

Renewable electricity for

Supporting EU manufacturing and reducing transport distances

Resource efficiencies help make Viaflo a more sustainable product[7]

Facilities committed to continuous environmental improvement

Reduced packaging and waste

Renewable electricity for Viaflo

Manufacturing sites in the UK and Spain have purchased electricity from 100% renewable sources since 2015, and since 2016 in Ireland, substantially reducing carbon footprint.

Our passion and drive for sustainability shape our products

Renewable electricity for Viaflo

Supporting EU manufacturing and reducing transport distances

Resource efficiencies help make Viaflo a more sustainable product[7]

Facilities committed to continuous environmental improvement

Reduced packaging and waste

Facilities committed to continuous environmental improvement

All manufacturing sites certified to ISO 14001 for environmental management and have strict energy efficiency programmes in place.

ISO, International Organization for Standardization.

Our passion and drive for sustainability shape our products

Renewable electricity for Viaflo

Supporting EU manufacturing and reducing transport distances

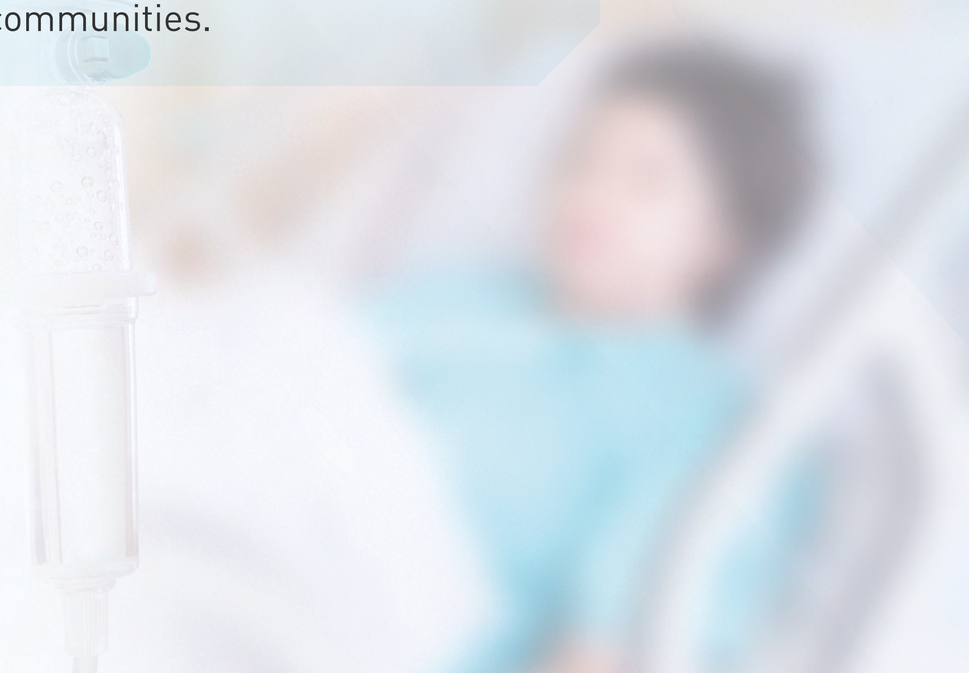
Resource efficiencies help make Viaflo a more sustainable product[7]

Facilities committed to continuous environmental improvement

Reduced packaging and waste

Supporting EU manufacturing and reducing transport distances

Almost 100% of **Viaflo** products currently sold on EU market are EU manufactured, providing 1000+ jobs and benefitting local communities.



Our passion and drive for sustainability shape our products

Renewable electricity for Viaflo

Supporting EU manufacturing and reducing transport distances

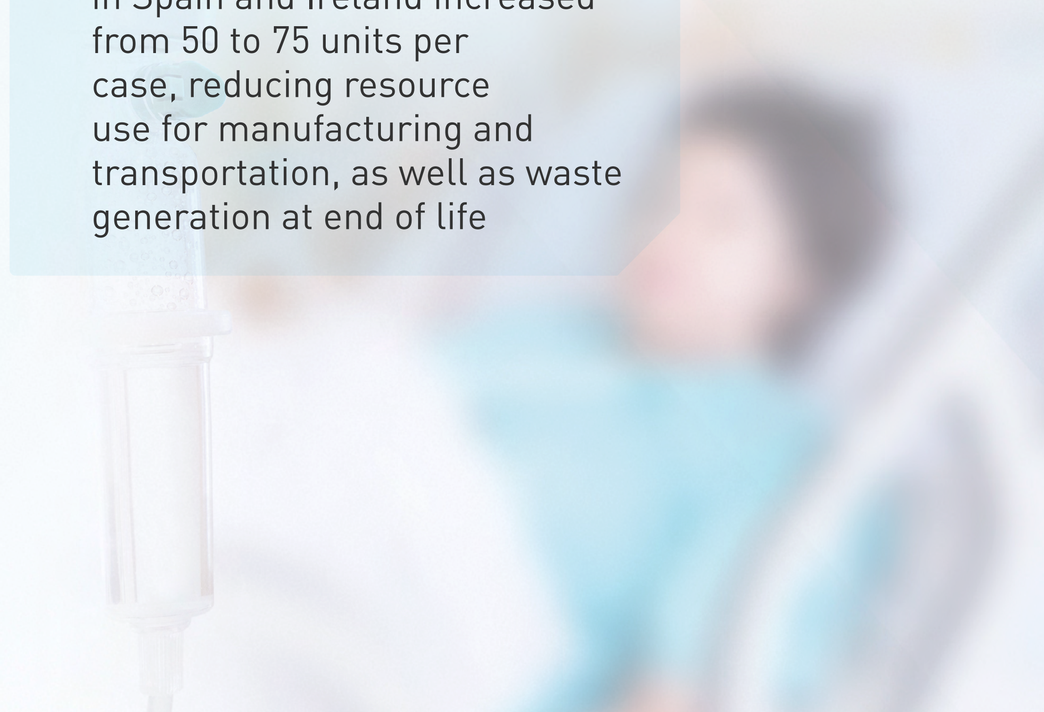
Resource efficiencies help make Viaflo a more sustainable product[7]

Facilities committed to continuous environmental improvement

Reduced packaging and waste

Reduced packaging and waste

- 2011 – **Viaflo** plastic overwrap size reduced by ~9%, saving an estimated 202 tonnes of material per year across four EU countries
- 2016 – Pack factor of 50 mL **Viaflo** product manufactured in Spain and Ireland increased from 50 to 75 units per case, reducing resource use for manufacturing and transportation, as well as waste generation at end of life



Our passion and drive for sustainability shape our products

Disposal of Viaflo IV bags

Viaflo primary IV bag

Potentially infectious and should be incinerated. **Viaflo** bag has a higher energy content than other forms of plastics, such as PVC. As such, incineration with energy recovery is recommended to reduce **Viaflo's** disposal impact.

Viaflo overwrap

Made from a multi-layered plastic film for maximum protection of enclosed **Viaflo** bag. This material composition is recyclable only by companies specialized in multi-layered plastics recycling.*

Viaflo cardboard box

Made from recycled material.*

PVC, Polyvinyl Chloride.

*Recyclable if segregated accordingly.

Baxter's commitment to sustainability

Our approach to corporate responsibility reinforces our mission to innovate in the development of products, therapies and services that save and sustain patients' lives.

Pharmaceuticals and medical devices significantly contribute to healthcare-related greenhouse gas emissions, so manufacturers have a responsibility to provide more sustainable products.

Product Sustainability Review (PSR):

- Underpins our sustainable design efforts
- Assesses environmental, health and safety, sustainability, and regulatory considerations and requirements across the value chain
- Key metrics illustrate progress on avoiding materials of concern, minimising customer waste and reducing carbon footprint
- Objectives are to continually improve Baxter's operations and help meet demand for more sustainable products

Baxter has been included in:

MEMBER OF Dow Jones Sustainability Indices In Collaboration with RobecoSAM

The ROBECOSAM Dow Jones Sustainability Index every year since it was created in 1999

Forbes | 2017 AMERICA'S BEST LARGE EMPLOYERS POWERED BY STATISTA

Forbes' 2017 list of America's best large employers

CR's 100 Best Corporate Citizens 2017

Corporate Responsibility Magazine's 100 Best Corporate Citizens list, for the 16th year running

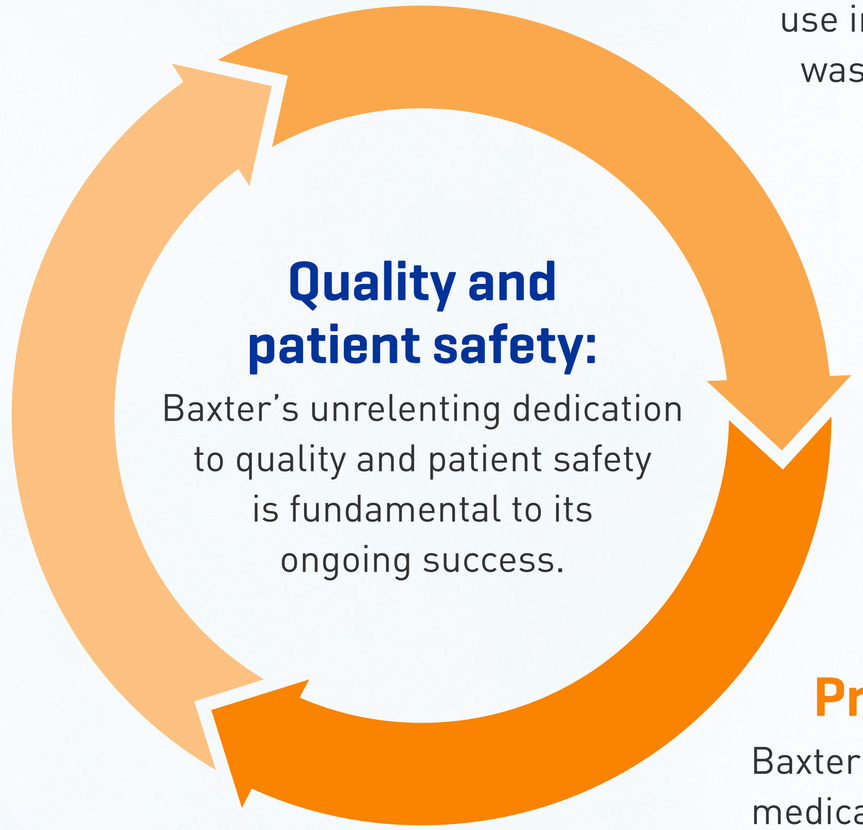
CLIMATE LEADERSHIP AWARDS

The 2018 Climate Leadership Awards — our commitment to responsible operations earned us an honourable mention for 'Organisational Leadership' from the Climate Registry

Baxter's commitment to sustainability

Material use:

Baxter innovates to reduce material use in products, manufacturing waste, packaging, and use of materials of concern.



Quality and patient safety:

Baxter's unrelenting dedication to quality and patient safety is fundamental to its ongoing success.

Sustainable design:

PSR and life-cycle assessment evaluate environmental performance and requirements for products across value chain, driving ongoing improvements.

Product end-of-life:

Baxter repairs and reuses electronic medical products when possible and collaborates to recycle medical waste and recapture materials when reuse is not an option.

PSR, Product Sustainability Review.

To learn more about Baxter's Corporate Responsibility initiatives and to read the company's report, please visit www.baxter.com/corporate-responsibility.page

Viaflo — for IV patient care, efficiency and sustainability in IV administration

- **Large portfolio** of **Viaflo** options
- Closed-system design helps reduce the **risk of contamination**
- **Overwrapped** for additional protection
- Multi-layered bag for **high compatibility** with a large array of drugs
- Port designed to **minimize risk of needlestick injury**
- **High admixture volumes** mean less manipulation

- **Minimal residual volume** helps ensure your patient receives the intended prescribed dose
- Validated with Baxter's **advanced reconstitution systems**
- **Pressure-cuff compatible**
- Can be **heated** in a warming cabinet
- Carton design **facilitates storage** and access to product
- **Environmentally friendly** and sustainable product and packaging

For safe and proper use of products mentioned herein, please refer to the Instructions for Use within the Summary of Product Characteristics.

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Summary of Product Characteristics for international use based upon the common English text approved in the EU.
Please note that this may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.
Note this product may not be available in your country of practice.

1. NAME OF THE MEDICINAL PRODUCT
Sodium Chloride 0.9% Intravenous Infusion BP
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium chloride: 9.0 g/l
Each ml contains 9 mg sodium chloride.
mmol/l: Na+ : 154 Cl-: 154.
pH: 4,5 -7
For the full list of excipients: see section 6.1
3. PHARMACEUTICAL FORM
Solution for infusion
Clear solution, free from visible particles.
4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Sodium Chloride 0.9% intravenous infusion is indicated for:
- Treatment of isotonic extracellular dehydration
- Treatment of sodium depletion
- Vehicle or diluent of compatible drugs for parenteral administration.

4.2. Posology and method of administration
Posology
Adults, older people and children:
Doses may be expressed in terms of mEq or mmol of sodium, mass of sodium, or mass of sodium salt (1 g NaCl = 394 mg, 17.1 mEq or 17.1 mmol of Na and Cl).
Fluid balance, serum electrolytes and acid-base balance should be monitored before and during administration, with particular attention to serum sodium 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 hospital acquired hyponatraemia (see sections 4.4, 4.5 and 4.8). Monitoring of serum sodium is particularly important for hypotonic fluids.

Sodium Chloride 0.9% intravenous infusion has a tonicity of 308 mOsm/l (approx.)

The infusion rate and volume depend on age, weight, clinical condition (e.g. burns, surgery, head-injury, infections),and concomitant therapy should be determined by the consulting physician experienced in intravenous fluid therapy (see sections 4.4. and 4.8).
Recommended dosage
The recommended dosage for treatment of isotonic extracellular dehydration and sodium depletion is:
- For adults : 500 ml to 3 litres/24h
- For babies and children: 20 to 100 ml per 24h and per kg of body weight, depending of the age and the total body mass.

The recommended dosage when used as a vehicle or diluent ranges from 50 to 250 ml per dose of medicinal product to be administered.
When Sodium Chloride 0.9 % is used as a diluent for injectable preparations of other drugs, the dosage and the infusion rate will also be dictated by the nature and the dose regimen of the prescribed drug.
Method of administration
The solution is for administration by intravenous infusion through a sterile and non-pyrogenic administration set, using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
The product should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless solution is clear, free from visible particles and the seal is intact
Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set.
Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. 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 infusion or during infusion through the injection site.
For information on incompatibilities and preparation of the product (with additives), please see sections 6.2 and 6.6.

4.3. Contraindications
The solution is contra-indicated in patient presenting hypernatraemia or hyperchloraemia.
The contra-indications related to the added medicinal product should be considered.
4.4. Special warnings and precautions for use
Fluid balance/renal function
Use in patients with (severe) renal impairment
Sodium Chloride 0.9% should be administered with particular caution to patients with or at risk of severe renal impairment. In such patients, administration of Sodium Chloride 0.9% may result in sodium retention. (See "Use in patients at risk for sodium retention, fluid overload and oedema" below; for additional considerations.)

Risk of fluid and/or solute overload and electrolyte disturbances
Depending on the volume and rate of infusion, intravenous administration of Sodium Chloride 0.9% can cause:
- Fluid and/or solute overload resulting in overhydration/hypervolemia and, for example, congested states, including central and peripheral oedema.
- Clinically relevant electrolyte disturbances and acid-base imbalance.

In general, the risk of dilutional states (retention of water relative to sodium) is inversely proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions. Conversely, the risk of solute overload causing congested states (retention of solute relative to water) is directly proportional to the electrolyte concentrations of Sodium Chloride 0.9% and its additions.

Special clinical monitoring is required at the beginning of any intravenous infusion. 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.

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 (see below).

Hyponatraemia
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 (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral 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, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

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Use in patients at risk for sodium retention, fluid overload and oedema
Sodium Chloride 0.9% should be used with particular caution, if at all, in patients with or at risk for:

- Hypernatraemia. Rapidly correcting hypernatraemia once adaptation has occurred may lead to cerebral oedema, potentially resulting in seizures, permanent brain damage, or death.
- Hyperchloraemia
- Metabolic acidosis, which may be worsened by prolonged use of this product, especially in patients with renal impairment.
- Hypervolaemia such as congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease.
- Iatrogenic hyperchloraemic metabolic acidosis (e.g., during intravenous volume resuscitation)
- Conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as patients with

o primary hyperaldosteronism,
o secondary hyperaldosteronism, associated with, for example,
- hypertension,
- congestive heart failure,
- liver disease (including cirrhosis),
- renal disease (including renal artery stenosis, nephrosclerosis) or pre-eclampsia.

Medications that may increase the risk of sodium and fluid retention, such as corticosteroids

Infusion reactions
Symptoms of unknown aetiology which can appear to be hypersensitivity reactions have been reported very rarely in association with infusion of Sodium Chloride 0.9 %. These have been characterized as hypotension, pyrexia, tremor, chills, urticaria, rash and pruritus. Stop the infusion immediately if signs or symptoms of these reactions develop. Appropriate therapeutic countermeasures should be instituted as clinically indicated.

Specific patient groups
The consulting physician should be experienced in this product's use and safety in these special populations that are especially sensitive to rapid changes in serum sodium levels.

Rapid correction of hyponatraemia and hypernatraemia is potentially dangerous (risk of serious neurologic complications). See section "Hyponatraemia/ hypernatraemia" above.

Paediatric population
Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes. Repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.
Geriatric population
When selecting the type of infusion solution 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.
For information on preparation of the product and additives, please see section 6.6.

4.5. Interaction with other medicinal products and other forms of interaction
Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may 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 include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues include: 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 of Sodium Chloride 0.9%. Administration of Sodium Chloride 0.9% may result in decreased lithium levels. Corticoids/Steroids and carbenoxolone, are associated with the retention of sodium and water (with oedema and hypertension). See Section 4.4 Special warnings and precautions for use.

4.6. Fertility, pregnancy and lactation
There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride 0.9%. Sodium Chloride 0.9% should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see section 4.4, 4.5 and 4.8).

Caution is advised with patients with pre-eclampsia (See Section 4.4. Special warnings and precautions for use).
When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation has to be considered separately.

4.7. Effects on ability to drive and use machines
No studies have been conducted on the influence of Sodium Chloride 0.9% 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. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

System Organ Class (SOC)	Adverse reactions (Preferred Term)	Frequency
Nervous system disorders	Tremor Acute hyponatraemic encephalopathy*	Not known
Metabolism and nutrition disorders	Hospital acquired hyponatraemia*	Not known
Vascular disorders	Hypotension	Not known
Skin and subcutaneous tissue disorders	Urticaria Rash Pruritus	Not known
General disorders and administration site conditions:	Infusion site reactions, such as • Infusion site erythema, • Vein irritation, Injection site streaking, burning sensation, • Local pain or reaction , Infusion site urticaria • Infection at the site of injection, • Venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia • Pyrexia • Chills	Not known

*Hospital acquired hyponatraemia may cause irreversible brain injury and death, due to development of acute hyponatraemic encephalopathy, frequency unknown (see sections 4.2. 4.4, 4.5).

The following adverse reactions have not been reported with this product but may occur:

- Hypernatraemia (eg. when administered to patients with nephrogenic diabetes insipidus or high nasogastric output)
- Hyperchloraemic metabolic acidosis
- Hyponatraemia, which may be symptomatic. Hyponatraemia may occur when normal free water excretion is impaired. (eg SIADH or postoperative)

General adverse effects of sodium excess are described in section 4.9 Overdose.
Additives
When Sodium Chloride 0.9% is used as a diluent for injectable preparations of other drugs, the nature of additives will determine the likelihood of any other undesirable effect.
If an adverse event occurs the patient should be evaluated and appropriate counter measures be started, if needed the infusion should be stopped. The remaining part of the solution should be kept for investigation if deemed necessary.
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 the Yellow Card Scheme. Website: www.mhra.gov.uk/ yellowcard

4.9. Overdose
General adverse effects of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.
An excessive volume of Sodium Chloride 0.9% may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialised physician.
Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.
When Sodium Chloride 0.9% is used as a diluent for injectable preparations of

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other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: "Other IV Solution Additives"
ATC code: B05XX

Sodium Chloride 0.9% intravenous infusion is an isotonic solution, with an approximate osmolarity of 308 mOsm/l.
The pharmacodynamic properties of the solution are those of the sodium and chloride ions in maintaining the fluid and electrolyte balance. 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.

5.2. Pharmacokinetic properties

Sodium is predominantly excreted by the kidney, but there is extensive renal reabsorption.
Small amounts of sodium are lost in the faeces and sweat.

5.3. Preclinical safety data

The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.

6. PHARMACEUTICALS PARTICULARS

6.1. List of excipients

Water for Injections.

6.2. Incompatibilities

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used.
See section 6.6 for further instructions on the use of the product with additives

6.3. Shelf life

Shelf life as packaged:
50 ml bag: 15 months
100 ml bag: 2 years
250 and 500 ml bags: 2 years
1000 ml bags: 3 years

In-use shelf life: Additives.
Chemical and physical stability of any additive at the pH of Sodium Chloride 0.9% Intravenous Infusion 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

50 and 100 ml bags: Do not store above 30°C.
250, 500 and 1000 ml bags: This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bag sizes: 50, 100, 250, 500 or 1000 mL
The bags known as Viaflo are composed of polyamide co-extruded plastic (PL-2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/ polypropylene.

Pack sizes:

- 50 bags of 50 ml per carton
- 75 bags of 50 ml per carton
- 1 bag of 50 ml
- 50 bags of 100 ml per carton
- 60 bags of 100 ml per carton
- 1 bag of 100 ml
- 30 bags of 250 ml per carton
- 1 bag of 250 ml
- 20 bags of 500 ml per carton
- 1 bag of 500 ml
- 10 bags of 1000 ml per carton
- 1 bag of 1000 ml

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Please see section 4.2 for information regarding the method of administration.
Before adding a drug, verify it is soluble and stable in water at the pH range of the Sodium Chloride 0.9% Intravenous Infusion solution. Additives may be introduced before infusion or during infusion through the injection site.
It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium Chloride 0.9% Intravenous Infusion solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.
When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.
Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.
Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

Instructions for use

Opening

- Remove the Viaflo container from the overpouch just before use.
- Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired
- Check solution for limpidity and absence of foreign matter. If solution is not clear or
  contains foreign matter, discard the solution.

Preparation for administration

Use sterile material for preparation and administration.

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

Techniques for injection of additive medications

Warning: Additives may be incompatible.
To add medication before administration

- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- 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

- Close clamp on the set
- Disinfect medication site.
- Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture resealable medication port and inject.
- Remove container from IV pole and/or turn to an upright position.
- Evacuate both ports by tapping gently while the container is in an upright position.
- Mix solution and medication thoroughly.
- Return container to in use position, re-open the clamp and continue administration.

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