PRESCRIBING INFORMATION

5% Dextrose Injection

Sterile Solution for Infusion, Intravenous

Mfr. Std.

In **free***flex*®/ **free***flex*®⊕ containers

Intravenous Fluid and Nutrient Replenisher

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5% Dextrose Injection

In **free***flex*®/ **free***flex*®✪ containers

SUMMARY PRODUCT INFORMATION

5% Dextrose Injection is a sterile nonpyrogenic solution for fluid replenishment and caloric supply in single dose containers for intravenous administration. It contains no bacteriostatic or antimicrobial agents or added buffers. The composition, osmolarity and approximate pH of 5% Dextrose Injection are shown in Table 1.

Table 1. Product information

Product Name	DIN	Package size (mL)	Composition**	Osmolarity (calc.) (mOsmol/L)	pH	Caloric value (kcal/L)
5% Dextrose Injection	02403536	50 100 250 500 1000	**50 g / L anhydrous dextrose*** **(anhydrous glucose)** which corresponds to 55 g / L Dextrose monohydrate (Glucose monohydrate)	252	5 (3.5–6.5)	170

*The dextrose is purified from corn and may contain fructose.

** Non-medicinal ingredients: Water for Injection (q.s.) and sodium hydroxide or hydrochloric acid to adjust pH (q.s.).

Table 2. **Description of the free*flex*® and the free*flex*® ✪ systems**

free*flex*® container	**free*flex*®✪ container**
DESCRIPTION	
• The primary container consists of a bag and two ports with stoppers.	• Same as **free*flex*®** container
• The secondary packaging is an overwrap.	• Same as **free*flex*®** container

free*flex*® container	**free*flex*®✪ container**
• The **free*flex*®** plastic container is fabricated from a specially formulated polyolefines multilayer film. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. The **free*flex*®** bags are slightly overfilled. It is guaranteed that the extractable volume conforms at the end of shelf-life. Results of the toxicological evaluation show that the primary materials of the **free*flex*®** packaging system do not show any toxic potential even under severe extraction conditions.	• Same as **free*flex*®** container
PORTS	
• Two ports, with white and blue stoppers capped with tamper-evident covers.	• Two ports, with light blue and blue stoppers capped with tamper-evident covers.
• The **white** stopper on the left port, with the arrow pointing towards the bag, is the medication/injection port.	• The **light blue** stopper on the left port, with the arrow pointing towards the bag is the medication port. It has a threaded Luer-Lock connector to secure a syringe once the tamper-evident cover is broken off.
• The blue port with the arrow pointing away from the bag is the administration port.	• The blue port with the arrow pointing away from the bag is the administration port.
• The addition of drugs to **free*flex*®** bag via the medication port uses a syringe with a 19 to 22 gauge blunt fill needle to puncture the medication port and inject medication into the bag.	• The addition of drugs to the **free*flex*®** ✪ bag via the medication port is needle free. This can be performed by securely fastening the syringe to the Luer-Lock, to inject the medication into the bag. After additions, the medication port can be marked with a permanent red protective cap to indicate medication has been added.

Addition of medication should be accomplished using complete aseptic technique.

ACTIONS

5% Dextrose Injection has a value as a source of water and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS

5% Dextrose Injection is indicated as a source of water and calories.

CONTRAINDICATIONS

5% Dextrose Injection is contraindicated in the following conditions:

- Hypersensitive to any ingredient in the formulation or component of the container. For a complete listing, see DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Prescribing Information.
- Clinically significant hyperglycemia.
- Known allergy to corn or corn products since dextrose in the product is purified from corn.

WARNINGS AND PRECAUTIONS

General

Normal physiologic isotonicity range is approximately 280-310 mOsmol/liter. Rapid administration of a large volume of 5% Dextrose Injection may cause hemolysis due to its relatively low osmolarity (see Table 1).

5% Dextrose Injection (electrolyte-free dextrose aqueous solution) should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglomeration or hemolysis.

Excessive administration of this potassium-free product may result in significant hypokalemia.

5% Dextrose Injection should be used with caution in patients with overt or subclinical diabetes mellitus.

Caution must be exercised in the administration of parenteral fluids to patients receiving corticosteroids or corticotropin.

This product may contain fructose as an impurity in the dextrose material. Exercise caution when this product is used in patients with hereditary fructose intolerance due to aldolase deficiency. In these patients, fructose may result in hypoglycemia, metabolic acidosis, liver toxicity which manifests as vomiting, nausea, sweating, jaundice, hemorrhage, seizures or coma or even death. The severity of the reactions is dependent on the amount and duration of fructose intake.

WARNING: These products contain aluminum which may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature

neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Risk of Air Embolism

Do not connect flexible plastic containers in series connections. Such use could result in air embolism due to possible 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.

Hypersensitivity Reactions

Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Dextrose injection (see Adverse Reactions).

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Dilution and other effects on serum electrolytes

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of dextrose can cause:

- Hyperosmolality, osmotic diuresis and dehydration
- Hypo- or hyperosmotic hypoosmolality (see below),
- Electrolyte disturbances such as
  - Hyponatremia,
  - Hypokalemia,
  - Hypophosphatemia,

- Hypomagnesemia,

- Overhydration/Hypervolemia and, for example, congested states, including pulmonary congestion and edema.

The above effects do not only result from the administration of electrolyte-free fluid but also from dextrose administration. In addition:

- An increase in serum glucose concentration is associated with an increase in serum osmolarity. Osmotic diuresis associated with hyperglycemia can result in or contribute to the development of dehydration and in electrolyte losses.

- Hyperglycemia also causes a transcellular shift of water, leading to a decrease in extracellular sodium concentrations and hyponatremia.

- Since the dextrose in 5% Dextrose Injection is metabolized, infusion of 5% Dextrose Injection corresponds to increasing the body's load of free water, possibly leading to hypoosmotic hyponatremia.

Monitoring of serum sodium is particularly important. 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 syndrome of inappropriate antidiuretic hormone secretion (SIADH)), due to the risk of hospital-acquired hyponatremia.

Hypoosmotic Hyponatremia

Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk for developing hypoosmotic hyponatremia is increased, for example,

- in children

- in elderly patients

- in women

- postoperatively

- in persons with psychogenic polydipsia

The risk for developing encephalopathy as a complication of hypoosmotic hyponatremia is increased, for example,

- in pediatric patients (≤16 years of age)

- in women (in particular, premenopausal women)

- in patients with hypoxemia

- in patients with underlying central nervous system disease

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.

Particular caution is advised in patients at increased risk of and from water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycemia or possibly required insulin administration (see below).

Preventive and corrective measures must be instituted as clinically indicated.

Hyperglycemia

Rapid administration of dextrose solutions may produce substantial hyperglycemia which may result in or contribute to electrolyte losses, dehydration and hypovolemia due to osmotic diuresis and a hyperosmolar syndrome. At certain clinical conditions it also may increase the risk of hypoosmotic hyponatremia by shifting of intracellular water to extracellular space.

Use with caution in critically ill patients in whom hyperglycemia commonly occurs due to diabetes, impaired glucose tolerance, impaired fasting glucose, or is stress-induced.

Hyperglycemia may increase the risk of cardiac complications, infection, systemic sepsis, acute renal failure and even death in certain clinical conditions, especially in acute stress conditions.

In order to avoid hyperglycemia the infusion rate should not exceed the patient's ability to utilize glucose.

To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted to the level suitable to the patient's ability to utilize glucose and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

5% Dextrose Injection 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),

- thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolization of pyruvate),

- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load (see above)

- patients with ischemic stroke. Hyperglycemia 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 hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.

- Newborns (see Special Populations/Pediatrics)

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

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 intakes while avoiding overfeeding can prevent these complications.

MONITORING AND LABORATORY TESTS

Clinical evaluation and periodic laboratory determination are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Carcinogenesis and Mutagenesis

Studies with dextrose injection have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

SPECIAL POPULATIONS

Pregnancy and Lactation

There are no adequate data from the use of dextrose injection in pregnant or lactating women.

It is not known whether dextrose injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 5% Dextrose Injection should be given to a pregnant woman only if clearly needed.

Studies have not been conducted to evaluate the effects of dextrose injection on labour and delivery. Caution should be exercised when administering this drug during labor and delivery.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 5% Dextrose Injection is administered to a nursing woman.

Intrapartum maternal intravenous dextrose infusion may result in fetal insulin production, with an associated risk of fetal hyperglycemia and metabolic acidosis as well as rebound hypoglycemia in the neonate.

Healthcare practitioners should carefully consider the potential risks and benefits for each specific patient before administering 5% Dextrose Injection.

Pediatrics

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

Pediatric Glycemia-related Issues

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

HYPOglycemia in the newborn can cause:

- prolonged seizures,
- coma, and
- cerebral injury

HYPERglycemia has been associated with

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

Pediatric Hyponatremia-related Issues

Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatremia as well as for developing hyponatremic encephalopathy.

Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

Plasma electrolyte concentrations should be closely monitored in the pediatric population.

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

Geriatrics

Clinical studies of dextrose injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or drug therapy.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

The list of adverse reactions in this Prescribing Information is based on post-marketing reports (see below).

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid and administration set for examination if deemed necessary.

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 anaphylactic/anaphylactoid reactions, including reactions with mild manifestations, e.g., Pruritus, and reactions with severe manifestations, e.g., Bronchospasm, Cyanosis, Angioedema and Hypotension; Pyrexia, Chills

METABOLISM AND NUTRITION DISORDERS: Hyperglycemia

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Infusion site reactions including, Infusion site phlebitis, Infusion site erythema

Other adverse reactions reported with other similar products include:

- Hyponatremia, which may be symptomatic (see “Hypoosmotic hyponatremia” in WARNINGS AND PRECAUTIONS).

- Hyponatremic encephalopathy

DRUG INTERACTIONS

Studies have not been conducted to evaluate additional drug/drug or drug/food interactions with dextrose injection.

Both the glycemic effects of dextrose injection and its effects on water and electrolyte balance should be taken into account when using 5% Dextrose Injection in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.

Caution is advised when administering 5% Dextrose Injection to patients treated with 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 hyponatremia following treatment with intravenous fluids (See Warnings and Precautions and Adverse Reactions)

Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsycotics, opioids.

Drugs 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 5% Dextrose Injection to patients treated with drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics (e.g., oxcarbazepine).

DOSAGE AND ADMINISTRATION

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, as well as concomitant therapy. For pediatric patients, consult a physician experienced in pediatric intravenous fluid therapy.

5% Dextrose Injection has an osmolarity of 252 mOsmol/L. Administration of hyperosmolar solutions may cause venous irritation and phlebitis.

A gradual increase of flow rate should be considered when starting administration of dextrose-containing products.

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Do not administer unless solution is clear and the seal is intact.

5% Dextrose Injection is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use of an in-line filter is recommended during administration of all parenteral solutions where possible.

Additives may be incompatible. When introducing additives to 5% Dextrose Injection, the instructions for use of the medication to be added and other relevant literature must be consulted.

Those additives known to be incompatible with dextrose should not be used. Consult with pharmacist if available. If in the informed judgment of the physician it is deemed advisable to introduce additives, aseptic technique must be used.

Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of 5% Dextrose Injection is appropriate.

After addition, check for a possible color change and/or the appearance of precipitates, insoluble complexes or crystals. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

For single use only. After opening the **free***flex*® and **free***flex*® ✪ IV containers, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used **free***flex*® and **free***flex*® ✪ IV containers. Discard any unused portion.

OVERDOSAGE

Excess administration of 5% Dextrose Injection can cause hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications (see Warnings and Precautions and Adverse Reactions). For example, severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal.

Interventions include discontinuation of 5% Dextrose Injection administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

Clinically significant overdose of 5% Dextrose Injection may, therefore, constitute a medical emergency.

If you think you, or a person you are caring for, have taken too much 5% Dextrose Injection, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

DOSAGE FORM, COMPOSITION AND PACKAGING

How Supplied

Table 1 shows the composition, osmolarity, approximate pH, calories/litre, ionic concentration and available sizes of 5% Dextrose Injection.

Each 100 mL of 5% Dextrose Injection contains:

Dextrose monohydrate (5.5 g) corresponding to anhydrous Dextrose	5.0 g
Water for injection	q.s. to 100 mL
Sodium hydroxide or hydrochloric acid to adjust pH	q.s
Titratable acidity (mmol NaOH/L)	< 1

5% Dextrose Injection is supplied in 50, 100, 250, 500 and 1000 mL **free***flex*® and **free***flex*® ✪ containers (polyolefin bags with overwrap). The polyolefin bags are PVC-free, DEHP-free and are not made with natural rubber latex.

DIRECTIONS FOR USE

WARNINGS:

Do not administer unless the solution is clear, virtually colourless and the seal is intact.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

From a microbiological point of view, the medicinal product should be used immediately after addition of additives. Do not store. Discard unused portion.

The physician should discontinue the infusion if adverse reactions occur.

CAUTIONS:

Aseptic technique is required including when mixing with medication. This solution is intended for intravenous administration using sterile equipment. When the 5% Dextrose Injection is used for intermittent intravenous infusion, the intravenous administration set should be replaced every 24 hours. If 5% Dextrose Injection is to be administered as a continuous infusion and if there is no manipulation of the set during a continuous administration, then the administration set should be changed every 96 hours or as per hospital practice.

Do not remove the **free***flex*® and **free***flex*®✪ IV containers from its overwrap until immediately before use.

Before use, perform the following checks: Read the label. Ensure solution is the one ordered and is within the expiration date.

Parenteral drug products should be inspected visually in good light for cloudiness, haze, particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear.

The **free***flex*® and **free***flex*®⊕ IV containers should also be inspected for leakage or damage, ensuring that the seals are intact. Any container which is suspect should not be used. This preservative free solution is intended for single use only. Any unused portion or waste materials should be disposed in accordance with local requirements.

5% Dextrose Injection (5.0 g/100 mL) should be used immediately after insertion of the administration set. Do not vent.

I. Infusion Application with free*flex*® container

Before administering the product in plastic bags to patient, refer to **INSTRUCTIONS FOR INFUSION APPLICATION WITH free*flex*® CONTAINER**, and review the following directions:

To add medication

WARNING: Some additives may be incompatible.

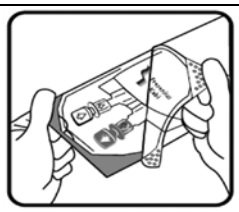
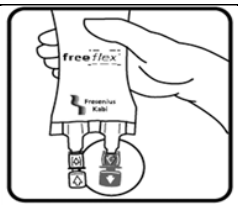
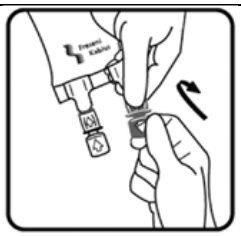
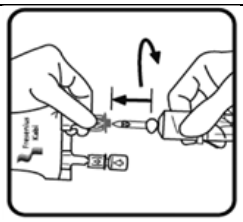
To add medication before solution administration

1. Prepare medication site.
2. Using a syringe with a 19 to 22 gauge blunt fill needle, puncture the resealable medication port and inject medication.
3. Mix solution and medication thoroughly.
4. Place container to in-use position and begin administration.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using a syringe with a 19 to 22 gauge blunt fill needle, puncture the resealable medication port and inject medication.
4. Remove container from IV pole and place in an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

INSTRUCTIONS FOR INFUSION APPLICATION WITH free*flex*® CONTAINER:

1.		Check the solution composition, lot number and expiry date, inspect the container for damage or leakage. If damaged do not use.
2.		Place the bag on a clean, flat surface. Peel open over-wrap.
3.		Identify the blue infusion port (encircled on the right side). This is the administration port. The white port (on the left side) is the medication port where medication is to be injected.
4.		Place and keep the bag on a clean, flat surface. Break off the blue tamper-evident cover from the freeflex® infusion port.
5.		Close roller clamp of the administration set. Insert the spike until the clear plastic collar of the port meets the shoulder of the spike.
6.	Use a non-vented standard infusion set, or if using a vented set, close air inlet.	
7.	Hang the bag on the infusion stand. Press drip chamber to get fluid level. Prime infusion set. Connect and adjust the flow rate.	

II. Needle-Free Drug addition to free*flex*® container with a Luer-Lock Syringe

To add medication

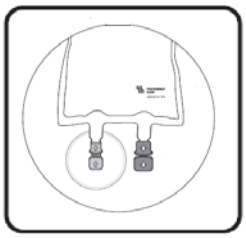
WARNING: Some additives may be incompatible.

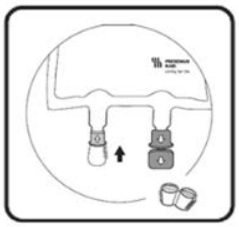
To add medication before solution administration and administering the product in plastic bags to patient, refer to **INSTRUCTIONS FOR NEEDLE-FREE DRUG ADDITION TO free*flex*® CONTAINER WITH A LUER-LOCK SYRINGE**, and review the following directions:

To add medication <u>during</u> solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Fasten the needleless, loaded syringe to the threaded Luer-Lock connection of the light blue **free***flex*® medication port and inject medication.
4. Remove container from the IV pole and place in an upright position.
5. Evacuate both ports by tapping and squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
7. Return container to in-use position and continue administration.

INSTRUCTIONS FOR NEEDLE-FREE DRUG ADDITION TO free*flex*® CONTAINER WITH A LUER-LOCK SYRINGE:

1.		Using an aseptic technique and observing standard precautions, prepare a syringe with a Luer-Lock. Place the bag on a clean, flat surface. Remove the overwrap. Identify the light blue **free***flex*® injection port (encircled on the left side).
2.		Break off the light blue tamper evident cover from the freeflex® injection port. The membrane below the light blue cover is sterile; disinfection of the membrane is not necessary.
3.		Hold the light blue **free***flex*® injection port with your fingers behind the finger guard. Connect the Luer-Lock of the syringe with the injection port of the **free***flex*® and inject the medication into the bag, then remove the syringe. The rigid port construction supports a safe and convenient handling.

4.		If no further additions are required, mark the injection port with the provided red protective cap* to indicate that the bag is filled with a drug and attach the label with detailed information to the bag. **caps cannot be removed once fastened.*
5.	Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.	
6.	Break-off the tamper-evident cover from the blue administration port.	
7.	Use a non-vented standard administration set or if using a vented set, close air inlet.	
8.	Close roller clamp of the administration set. Insert the spike until the clear plastic collar of the port meets the shoulder of the spike.	
9.	Hang the bag on the infusion stand. Press drip chamber to level fluid. Prime infusion set. Connect and adjust the flow rate.	

STORAGE

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

Store at 15 °C to 25 °C

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

REFERENCE:

1. 5% Dextrose Injection, USP; Solution for Infusion; submission control 227512, PRESCRIBING INFORMATION, Baxter Corporation, June 11, 2019.

If you want more information about 5% Dextrose Injection:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (https://www.fresenius-kabi.com/en-ca), or by calling 1-877-821-7724.

This Prescribing Information was prepared by:

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