PRESCRIBING INFORMATION

Ringer's Injection, USP
In VIAFLEX Plastic Container

Parenteral Replenisher

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Ringer's Injection, USP
In VIAFLEX Plastic Container

SUMMARY PRODUCT INFORMATION

Ringer's Injection, USP is a sterile, nonpyrogenic solution and contains no bacteriostatic or antimicrobial agents or added buffers. The composition, osmolarity and approx. pH of Ringer's Injection, USP is shown in Table 1.

Table 1	DIN	Size (mL)	Composition (g/L)			Osmolarity (mOsmol/L)	pH	Ionic Concentration (mmol/L)				Caloric Content (kcal/L)
			Sodium Chloride, USP	Calcium Chloride Dihydrate, USP	Potassium Chloride, USP			Sodium	Potassium	Calcium	Chloride	
Ringer's Injection, USP	00060925	1000	8.60	0.33	0.30	310	5.0 – 7.5	147	4	2.24	156	0

The Viaflex plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic).

The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g. di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

Normal physiologic isotonicity range is approximately 280-310 mOsmol/L. Administration of substantially hypotonic solutions may cause hemolysis and administration of substantially hypertonic solutions may cause vein damage.

ACTIONS

Ringer's Injection, USP is a source of water for hydration and provides electrolytes. It is capable of inducing diuresis depending on the clinical conditions of the patient.

Solutions which are polyelectrolytic have value in maintaining or replenishing electrolytes. See Table 1 for ionic concentrations.

INDICATIONS AND CLINICAL USE

Ringer's Injection, USP is indicated as a source of water and electrolytes.

CONTRAINDICATIONS

Ringer's Injection, USP is contraindicated in the following conditions:

- Patients with hypersensitive to any ingredient in the formulation or component of the container. For more information, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section.

- Concomitant administration of ceftriaxone in newborns (≤ 28 days of age), even if separate infusion lines are used due to risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream.

- Simultaneous administration of ceftriaxone through the same infusion line (e.g., via Y-port/Y-site) in patients older than 28 days of age. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

WARNINGS AND PRECAUTIONS

General

Ringer's Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Ringer's Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's Injection, USP should not be administered simultaneously through the same administration set as blood because of the likelihood of coagulation.

The intravenous administration of Ringer's Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the solution.

In patients with diminished renal function, administration of Ringer's Injection, USP may result in sodium or potassium retention.

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 warrants such evaluation.

Caution must be exercised in the administration of Ringer's Injection, USP to patients receiving corticosteroids or corticotropin.

Risk of Air Embolism

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

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.

DRUG INTERACTIONS

Concomitant treatment with ceftriaxone and Ringer's Injection, USP is contraindicated in newborns (≤28 days of age), even if separate infusion lines are used (risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream) (see **CONTRAINDICATIONS**).

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Ringer's Injection, USP, through the same infusion line (e.g., via Y-port/Y-site) (See **CONTRAINDICATIONS**).

ADVERSE REACTIONS

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

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

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.

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

All injections in Viaflex plastic containers are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Additives may be incompatible. Compatibility of additives must be checked before adding medication. Those additives known to be incompatible should not be used. If in the informed judgment of the physician it is deemed advisable to introduce additives, use aseptic technique.

Thorough and careful mixing of any additive is mandatory. Do not store solutions containing additives.

DOSAGE FORMS, COMPOSITION AND PACKAGING

How Supplied

Table 1 shows the composition, osmolarity, approx pH, caloriesL, ionic concentration and available size of Ringer's Injection, USP.

Directions for use of Viaflex Plastic Container

WARNING: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air (approximately 15 mL) being drawn from the primary container before administration of the fluid from the secondary container is completed.

Do not remove unit from overwrap until ready to use.

To Open

Tear overwrap down side at slit and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration. Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality and safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found discard solution as sterility may be impaired.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

1. Prepare medication site.
2. Using a syringe and 20 - 22 gauge needle, puncture re-sealable rubber plug at target area and inject. Multiple additions may be made in this manner.
3. Mix solution and medication thoroughly. For high density medications such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

Storage

Store between 15ºC and 25ºC.

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