SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCTS

RINGER LACTATE SOLUTION FRESENIUS - FREEFLEX

RINGER LACTATE SOLUTION FRESENIUS - KABIPAC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride:	6.00 g/l
Sodium Lactate:	3.17 g/l
Potassium Chloride:	0.40 g/l
Calcium Chloride Dihydrate:	0.27 g/l

Na^+ 131 mmol/l
K^+ 5.36 mmol/l
Ca^{+2} 1.84 mmol/l
Cl^- 112 mmol/l
Lactate $^-$ 28.3 mmol/l

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for I.V infusion.
Clear and colourless solution
Theoretical osmolarity: 278 mOsm/l
pH: 5.0 – 7.0

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Source of water and electrolytes.
- Regulation or maintenance of metabolic acidosis (except lactic acidosis).

4.2. Posology and Method of Administration

Posology

Adults, the elderly and children:

The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, and concomitant therapy.

Recommended dosage:

The amount of Ringer Lactate solution Fresenius needed to restore normal blood volume is 3 to 5 times the volume of lost blood.

The recommended dosage is:
- for adults: 500 ml to 3 L/24h
- for babies and children: 20 ml to 100 ml/kg/24 h

Administration rate:

The infusion rate is usually 40 ml/kg/24h in adults.

In pediatric patients the infusion rate is 5 ml/kg/h on average but the value varies with age: 6-8 ml/kg/h for infants, 4-6 ml/kg/h for toddlers, and 2-4 ml/kg/h for schoolchildren. In children with burns, the dose is on average 3.4 ml/kg/percent burn at 24 h post-burn and 6.3 ml/kg/percent burn at 48 h. In severely head-injured children the dose is on average 2850 ml/m².
Infusion rate and total volume can be higher in surgery or in case of need.

Note:
- infants and toddlers: age ranges from about 28 days to 23 months (a toddler is an infant who can walk)
- children and schoolchildren: age ranges from about 2 years to 11 years.

Administration:

The administration is performed by intravenous route using sterile and non-pyrogenic equipment.

4.3. Contraindications

As for other calcium-containing infusion solutions, concomitant administration of ceftriaxone and Ringer Lactate solution 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'sblood stream). For patients over 28 days of age please see section 4.4.

Ringer Lactate solution is also contraindicated in patients with:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Extracellular hyperhydration or hypervolaemia
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated cardiac failure
- Hyperkalaemia
- Hypercalcaemia
- Metabolic alkalosis
- Ascitic cirrhosis
- Severe metabolic acidosis
- Conditions associated with increased lactate levels (hyperlactataemia) including lactic acidosis, or impaired lactate utilization, such as severe hepatic insufficiency
- Concomitant digitalis therapy (see section 4.5 Interactions with other medicinal products and other forms of interaction).

4.4. Special warnings and precautions for use

Hypersensitivity 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.

Incompatibilities
Ceftriaxone
In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Ringer Lactate solution, through the same infusion line. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid. For patients under 28 days please see section 4.3.

Electrolyte balance
Hypernatraemia
Ringer Lactate solution should only be administered to patients with hypernatraemia after careful consideration of the underlying cause and alternative intravenous fluids. Monitoring of plasma sodium and volume status during treatment is recommended.

Ringer Lactate solution should be administered with particular caution in patients with conditions predisposing to hypernatraemia (such as adrenocortical insufficiency, diabetes insipidus or extensive tissue injury) and in patients with cardiac disease.

Hyperchloraemia
Ringer Lactate solution should only be administered to patients with hyperchloraemia after careful consideration of the underlying cause and alternative intravenous fluids. Monitoring of plasma chloride and acid-base balance during treatment is recommended.

Ringer Lactate solution should be administered with particular caution to patients with conditions predisposing to hyperchloraemia (such as renal failure and renal tubular acidosis, diabetes insipidus), and patients with urinary diversion or patients taking certain diuretics (carbonic anhydrase inhibitors, e.g., acetazolamide) or steroids (androgens, estrogens, corticosteroids) and in patients with severe dehydration.

Use in patients with potassium deficiency
Although Ringer Lactate solution has a potassium concentration similar to the concentration in plasma, it is insufficient to produce a useful effect in case of severe potassium insufficiency and therefore it should not be used for this purpose.

Use in patients at risk for hyperkalaemia
Ringer Lactate solution should be administered with particular caution to patients with conditions predisposing to hyperkalaemia (such as severe renal impairment or adrenocortical insufficiency, acute dehydration, or extensive tissue injury or burns) and in patients with cardiac disease.
The plasma potassium level of the patient must be particularly closely monitored in patients at risk of hyperkalaemia.

Use in patients at risk for hypercalcaemia
Calcium chloride is irritant, therefore care should be taken to prevent extravasation during intravenous injection and intramuscular injection must be avoided. Solutions containing calcium salts should be used with caution in patients with conditions predisposing to hypercalcaemia, such as patients with renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or a history of such calculi.

Fluid balance/renal function
Use in patients with renal impairment
Ringer Lactate solution should be administered with particular caution to patients with renal impairment. In such patients, administration of Ringer Lactate solution may result in sodium and/or potassium retention.

Risk of fluid and/or solute overload and electrolyte disturbances
Depending on the volume and rate of infusion, intravenous administration of Ringer Lactate solution can cause:

- fluid and/or solute overload resulting in overhydration and, for example, congested states, including pulmonary congestion and oedema.
- clinically relevant electrolyte disturbances and acid-base imbalance.

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 severe and life-threatening brain swelling caused by acute hyponatraemia.

Use in patients with hypervolaemia, overhydration or conditions causing sodium retention and oedema
Ringer Lactate solution should be administered with particular caution to hypervolaemic or overhydrated patients.
Due to the sodium chloride content, Ringer Lactate solution should be administered with particular caution to patients with conditions that may cause sodium retention, fluid overload and oedema, such as patients with primary hyperaldosteronism, secondary hyperaldosteronism (associated with, e.g., hypertension, congestive heart failure, renal artery stenosis, or nephrosclerosis), or preeclampsia (see also Section 4.5).

Acid-base balance
Use in patients at risk for alkalosis
Ringer Lactate solution should be administered with particular caution to patients at risk for alkalosis. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis. Seizure may be precipitated by the alkalosis induced by lactate but this is uncommon.

Other warnings
Administration of citrate anticoagulated/preserved blood
Due to the risk of coagulation precipitated by its calcium content, Ringer Lactate solution must not be added to or administered simultaneously through the same tubing with citrate anticoagulated/preserved blood.

Use in patients with type 2 diabetes
Lactate is a substrate for gluconeogenesis. Therefore glucose levels should be carefully monitored in patients receiving Ringer Lactate.

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

For information on incompatibilities and preparation of the product with additives, please see sections 6.2 and 6.6.

During long term parenteral treatment, a convenient nutritive supply must be given to the patient.

This medicinal product contains 301.3 mg sodium per 100 ml, equivalent to 15% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
This medicine contains 0.536 mmol (or 20.95 mg) potassium per 100 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

4.5. Interaction with other medicinal products and other forms of interaction

Ceftriaxone: See sections 4.3 and 4.4 for more information.

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 4.4 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.

Interaction related to the presence of sodium:
Caution is advised when administering Ringer Lactate solution to patients treated with drugs that may increase the risk of sodium and fluid retention (with oedemaand hypertension), such as corticosteroids.

Interaction related to the presence of potassium:
Because of its potassium content, Ringer Lactate solution should be administered with caution in patients treated with agents or products that can cause hyperkalaemia or increase the risk of hyperkalaemia, such as

- Potassium-sparing diuretics (amiloride, spironolactone, triamterene, alone or in association)
- Angiotensin converting enzyme inhibitors (ACEi) and angiotensin II receptor antagonists
- Tacrolimus, cyclosporin.

Administration of potassium in patients treated with such medications can produce severe and potentially fatal hyperkalaemia, particularly in patients with severe renal insufficiency.

Interaction related to the presence of calcium:
Administration of calcium may increase the effects of digitalis and lead to serious or fatal cardiac arrhythmia. Therefore, larger volumes or faster infusion rates should be used with caution in patients treated with digitalis glycosides.

- Caution is advised when administering Ringer Lactate solution to patients treated with thiazide diuretics or vitamin D, as these can increase the risk of hypercalcaemia.
- Bisphosphonates, fluoride, some fluoroquinolones and tetracyclines which are less absorbed (lower availability) when administered with calcium.

Interaction related to the presence of lactate (which is metabolized into bicarbonate):
Caution is advised when administering Ringer Lactate solution to patients treated with drugs for which renal elimination is pH dependent. Due to the alkalinizing action of lactate (formation of bicarbonate), Ringer Lactate solution may interfere with the elimination of such drugs.

- Renal clearance of acidic drugs such as salicylates, barbiturates, and lithium may be increased because of the alkalinisation of urine by the bicarbonate resulting from lactate metabolism.
- Renal clearance of alkaline drugs, such as sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetamine sulfate, phenfluramine hydrochloride) may be decreased.

4.6. Fertility, pregnancy and lactation

Ringer Lactate solution can be used safely during pregnancy and lactation as long as the electrolyte and fluid balance is controlled.

It is reminded that calcium crosses the placenta and is distributed into breast milk.

Ringer Lactate solution 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).

When a medication is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

4.7. Effects on ability to drive and use machines

There is no information on the effects of Ringer Lactate solution on the ability to operate an automobile or other heavy machinery.

4.8. Undesirable effects

The following adverse reactions (listed by MedDRA System Organ Class) have been reported spontaneously during the post-market experience.

Immune System Disorders	Hypersensitivity/Infusion reactions including Anaphylactic/Anaphylactoid reaction, possibly manifested by one or more of the following symptoms: Angioedema, Chest pain, Chest discomfort, Decreased heart rate, Tachycardia, Blood pressure decreased, Respiratory distress, Bronchospasm, Dyspnea, Cough, Urticaria, Rash, Pruritus, Erythema, Flushing, Throat irritation, Paresthesias, Hypoesthesia oral, Dysgeusia, Nausea, Anxiety, Pyrexia, Headache
Metabolism and Nutrition Disorders	Hyperkalaemia Hospital acquired hyponatraemia*
Nervous System Disorders	Acute hyponatraemic encephalopathy*
General Disorders and Administration Site Conditions	Infusion site reactions manifested by one or more of the following symptoms: Phlebitis, Infusion site inflammation, Infusion site swelling, Infusion site rash, Infusion site pruritus, Infusion site erythema, Infusion site pain, Infusion site burning

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

The following adverse reactions have been reported spontaneously during the use of other sodium-lactate containing solutions:

- Hypersensitivity: Laryngeal oedema (Quincke's oedema), skin swelling, Nasal congestion, Sneezing
- Electrolyte disturbances

- Hypervolaemia
- Panic attack
- Other infusion site reactions: Infection at the site of injection, Extravasation, Infusion site anesthesia (numbness)

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il and emailed to the Registration Holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

4.9. Overdose

An excessive volume or too high a rate of administration of Ringer Lactate solution may lead to fluid and sodium overload with a risk of oedema (peripheral and/or pulmonary), particularly when renal sodium excretion is impaired. In this case extra renal dialysis may be necessary.

Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion.

Excessive administration of calcium salts may lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi, and, in severe cases, cardiac arrhythmias and coma. Too rapid intravenous injection of calcium salts may also lead to many of the symptoms of hypercalcaemia as well as to chalky taste, hot flushes, and peripheral vasodilatation. Mild asymptomatic hypercalcaemia will usually resolve on stopping administration of calcium and other contributory drugs such as vitamin D. If hypercalcaemia is severe, urgent treatment (such as loop diuretics, haemodialysis, calcitonin, bisphosphonates, trisodium edetate) is required.

Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalaemia. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcaemic patients. Treatment of metabolic alkalosis due to bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium may be of particular importance.

When overdose is related to medications added to the solution infused, the signs and symptoms of over infusion will be related to the nature of the additive 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 symptomatic and supportive measures should be provided as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): B05BB01 "Electrolytes".

Ringer Lactate solution is an isotonic solution of electrolytes. The constituents of Ringer Lactate solution and their concentrations are designed to match those of plasma.
The pharmacological properties of the Ringer Lactate solution are those of its components (sodium, potassium, calcium, chloride and lactate).
The main effect of Ringer Lactate solution is the expansion of the extracellular compartment including both the interstitial fluid and the intravascular fluid.
The lactate is metabolised into bicarbonate, mainly in the liver, and produces an alkalinising effect on the plasma.

In healthy volunteers receiving Ringer Lactate solution, central venous pressure changes were associated with a secretion of atrial natriuretic peptide.
In healthy volunteers, Ringer Lactate solution decreased serum osmolality, increased blood pH, and the time until first urination was shorter than that with normal saline.
There is no significant changes in glucagon, norepinephrine, epinephrine, blood glucose and insulin levels in aortic surgery patients receiving Ringer Lactate solution.
When medication is added to Ringer Lactate solution, the overall pharmacodynamics of the solution will depend on the nature of the drug used.

5.2. Pharmacokinetic properties

The pharmacokinetic properties of the Ringer Lactate solution are those of the ions its composition includes (sodium, potassium, calcium and chloride).
Infusion of Ringer Lactate solution in normal hemodynamically stable adults does not increase circulating lactate concentrations.
The pharmacokinetics of D-lactate and L-lactate are similar.
The lactate in Ringer Lactate solution is metabolized by both oxidation and gluconeogenesis, predominantly in the liver, and bicarbonate is generatedby both processes over 1-2 h.
When medication is added to Ringer Lactate solution, the overall pharmacokinetics of the solution will depend on the nature of the drug used.

5.3. Preclinical safety data

Preclinical safety data of Ringer Lactate solution in animals are not relevant since its constituents are physiological components in animal and human plasma.
Toxic effects are not to be expected under the condition of clinical application.
The safety of potential additives should be considered separately.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for Injections, Hydrochloric acid, Sodium hydroxide.

6.2. Incompatibilities

Precipitation may occur when Ringer's lactate solution is mixed with solutions containing phosphate or carbonate.

6.3. Shelf life

Shelf life (Unopened):

The expiry date of the product is indicated on the packaging materials.

In-use shelf-life: Additives

From a microbiological point of view, the product should be used immediately after the addition of additives. If it is not administered immediately, the user assumes responsibility for in-use storage times and storage conditions. Normally, the mixture should be stored for no longer than 24 hours at 4-8°C, unless mixing has taken place under controlled and validated aseptic conditions.

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of container

Polyolefin bags (freeflex) of 250ml, 500 mL, 1000 mL with overwrap.
Polyethylene bottles (KabiPac) of 250 mL, 500 mL, 1000 mL.

Not all pack sizes may be marketed.

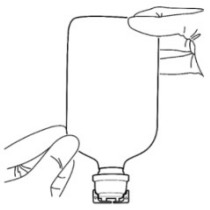
6.6. Special precautions for disposal

Use only if the solution for infusion is clear and the container undamaged.
Use immediately after opening the container.
After infusion, any unused solution must be discarded.

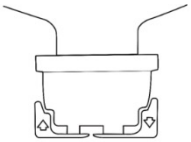
Please select the container that applies in your case (KabiPac, free*flex*).
The following instructions are designed as a guideline for handling the container.
For pharmaceutical preparations, the requirements for aseptic technique in accordance with the relevant guidelines must be observed.

Instructions for handling - KabiPac (PE container)

General preparation



- Make sure that you are using the desired solution for infusion.
- Check the expiry date and whether the liquid is clear and the container undamaged.



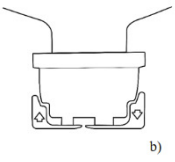
- Identify the correct port for the desired procedure:

  a) Arrow pointing towards the infusion bottle = injection port

  b) Arrow pointing away from the infusion bottle = infusion port

- The caps can be easily snapped off by pressing them back with the thumb just above the arrows. Immediately after snapping off the cap, no disinfection of the membrane is necessary.

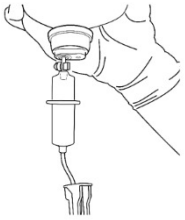
Preparing the infusion



- Identify the infusion port b) (arrow pointing away from the infusion bottle).
- Open the infusion port by pressing back with the thumb just above the arrows.

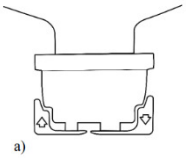
- Recommended: Use a commercial, non-vented, DIN infusion set.
- Close the air inlet (if present).
- Leave the roller clamp open (as delivered ex-factory).
- Use the spike to pierce the upright infusion bottle. Pierce vertically in the middle of the circle visible on the membrane.

- Recommended: Insert the spike using a slight twisting motion.
- Close the roller clamp.

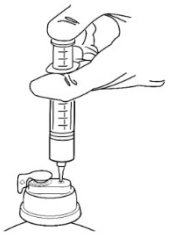


- Hang the infusion bottle on the infusion stand.
- Fill the drip chamber up to the mark (about half the drip chamber).
- Fill the infusion set.
- Attach the infusion set to the patient's venous access.
- Regulate the flow rate.

Optional: Injecting additional medicines, e.g. drug application via syringe



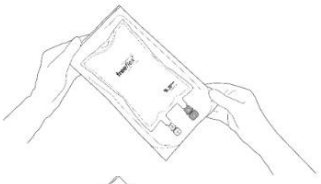
- Identify the injection port a) (arrow pointing towards the infusion bottle).
- Open the injection port by pressing back with the thumb just above the arrows.



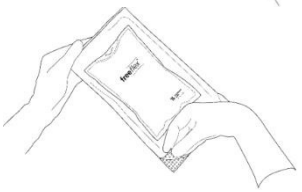
- Use only injection needles with an 18 to 23-gauge cannula size (19-gauge recommended).
- Insert the injection needle centrally and vertically.
- Administer the medicine into the KabiPac infusion bottle.
- Carefully mix the solution.

Instructions for handling - freeflex

General preparation



- Make sure that you are using the desired solution for infusion.
- Check the expiry date and whether the liquid is clear and the container undamaged.



- Remove the overwrap immediately before use.

- Identify the correct port for the desired procedure:
  a) Arrow pointing towards the infusion bag = white injection port
  b) Arrow pointing away from the infusion bag = dark blue infusion port

Preparing the infusion

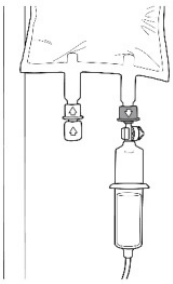
- Identify the dark blue infusion port b) (arrow pointing away from the infusion bag).

- Only use the solution if it is clear and the container is undamaged.

- To break off the caps, hold the dark blue infusion port with one hand and snap the cap back with the other hand. Immediately after snapping off the caps, no disinfection of the membrane is necessary.

- Recommended: Use a commercial, non-vented, DIN infusion set.
- Close the air inlet (if present).
- Leave the roller clamp open (as delivered ex-factory).
- Use the spike to pierce the dark blue infusion port of the infusion bag (on its side). Pierce centrally and vertically.
- Close the roller clamp.

- Hang the infusion bag on the infusion stand.
- Fill the drip chamber up to the mark (about half the drip chamber).
- Fill the infusion set.
- Attach the infusion set to the patient's venous access.
- Regulate the flow rate.



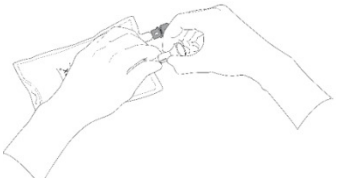
<u>Optional: Injecting additional medicines: Drug application via transfer adapter</u>

- Identify the white injection port a) (arrow pointing towards the bag).

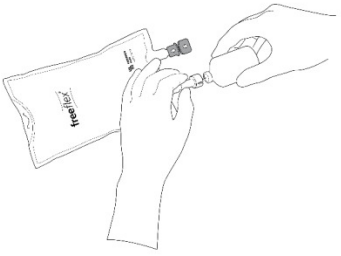
a)

- To break off the caps, hold the white infusion port with one hand and snap the cap back with the other hand. Immediately after snapping off the caps, no disinfection of the membrane is necessary.

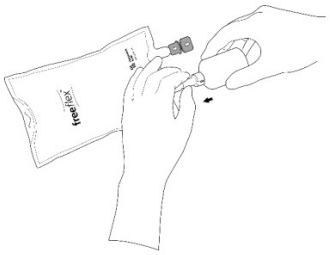
- Push the narrower end of the freeflex transfer adapter onto the white injection port until you hear an initial click.
- The needle tip is now inside the sterile chamber, which protects against contamination.



- Prepare the medication vial and attach it onto the freeflex transfer adapter.



- Push the freeflex transfer adapter further in the white injection port until you hear a second click and pierce the inner membrane.



- Hold the medication vial downwards and pump the solution for infusion into the medication vial by squeezing the bag.
- Dissolve the medication by careful shaking.

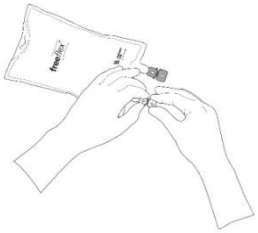
- Hold the medication vial upright and squeeze air in, so that the solution enters the bag from the medication vial.
- Repeat this process until all the fluid is transferred into the bag from the medication vial and the medication is thoroughly mixed.

- After mixing has taken place, carefully remove the medication vial and transfer adapter from the infusion bag.
- Mark off the white injection port a) after adding the medication by sealing it with a red freeflex cap.
- This will prevent any further addition of medicines and contamination of the injection port.

<u>Optional: Injecting additional medicines, e.g. drug application via syringe</u>

- Identify the white injection port a) (arrow pointing towards the bag).

- To break off the caps, hold the white infusion port with one hand and snap the cap back with the other hand. Immediately after snapping off the caps, no disinfection of the membrane is necessary.



- Recommendation: Prior to injecting, remove the volume of air inside the infusion bag to ensure a pressure-free injection.
- Use only injection needles with an 18 to 23-gauge cannula size (19-gauge recommended).
- Hold the injection port with your fingers behind the finger guard.

- Prepare the syringe and insert it vertically at the center of the white injection port.
- Administer the medicine from the syringe into the freeflex infusion bag.

- After mixing has taken place, remove the syringe from the infusion bag and mix the drug preparation thoroughly.
- Mark off the white injection port a) after adding the medication by sealing it with a red freeflex cap.
- This will prevent any further addition of medicines and contamination of the white injection port.

a)

7. MANUFACTURER

Fresenius Kabi Deuctschland GmbH,
Else-Kroner st.1, DE-61352, Bad Homburg, Germany.

8. MARKETING AUTHORISATION HOLDER

Neopharm (Israel)1996 LTD,
Hashiloach 6, POB 7063 Petach Tiqva 4917001.

9. MARKETING AUTHORISATION NUMBER

Ringer Lactate solution Fresenius - FreeFlex : 173-27-36648-99
Ringer Lactate solution Fresenius - KabiPac : 173-26-36657-99

Revised in November 2023 according to MOHs guidelines.