TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION- 0.9% isotonic sodium chloride solution injection, solution TURK ILAC VE SERUM SANAYI

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NAME OF THE MEDICINAL PRODUCT TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE Solution

QUALITATIVE AND QUANTITATIVE COMPOSITION Active substance: Each 100 ml of solution contains 0.9 g sodium chloride. Excipients: Water Osmolarity of solution is 308 mOsmol/l. Ionic concentrations of solution: - sodium: 154 mEq/l

- chloride: 154 mEq/l

PHARMACEUTICAL FORM Sterile solution for intravenous infusion

4.2. Posology and method of administration

Posology/frequency and duration of administration

The dosage is to be individualized by the physician depending on age, weight, clinical condition and in particular the patient's hydration state. Serum electrolyte concentrations must be monitored during treatment.

In general, 500 to 3000 ml per 24 hours for adults, adolescents and elderly and 20 to 100 ml/kg per 24 hours for infants and children is recommended for treatment of isotonic extracellular dehydration and sodium depletion unless otherwise prescribed by the doctor.

The dosage when used as a diluent should be determined by the nature and the dose regimen of the diluted drug. In general 50 to 250 ml of fluid is sufficient.

The frequency of administration and dosage is adjusted by the physician according to the clinical condition of the patient.

When TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is used as a diluent, the infusion rate will be adjusted according to the nature and the dose regimen of the diluted drug.

Method of administration:

The administration is to be made by intravenous route in a peripheral or central vein using sterile, apyrogenic sets.

See also section 6.6 for details on the administration.

Additional information on special populations:

Renal/Hepatic failure:

No dosage recommendations are made for this patient group, as there is no specific study for this population.

Pediatric population:

As in adults, dosage and infusion rate are directed by a physician depending on weight, clinical and biological condition of the patient and the concomitant treatment. In general 20 to 100 ml/kg per 24 h is recommended in this population.

Geriatric population:

As in adults, dosage and infusion rate are directed by a physician depending on weight, clinical and biological condition of the patient and the concomitant treatment.

Therapeutic indications

TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is indicated for:

- Treatment of isotonic extracellular dehydration
- Treatment of sodium depletion
- As diluent of compatible drugs for parenteral administration.

The solution is contraindicated in patient presenting hypernatremia or hyperchloremia. It is also contraindicated where the administration of sodium or chloride could be clinically detrimental.

Special warnings and precautions for use

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilution is inversely proportional to the electrolyte concentration. The risk of congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

The solution contains 154 mmol/l sodium (Na+) and 154 mmol/l chloride (Cl-); the osmolarity is about 308 mOsm/l and the pH is 5.5 (4.5-7.0).

Careful clinical monitoring is required at the beginning of any intravenous infusion. Administrations should be periodically and carefully monitored. Clinical and biological parameters, in particular serum electrolyte concentrations should be monitored. In preterm or term neonates, sodium retention can be seen because renal function is not yet fully developed. Repeated infusions of sodium chloride in neonates should therefore only be given after determination of the serum sodium levels.

Sodium-containing solutions should be used with caution in cases of hypertension, heart failure, peripheral or pulmonary edema, impaired renal function, preeclampsia, aldosteronism or other conditions and treatments with sodium accumulation (e.g. corticosteroid therapy).

Pseudohyponatremia is a condition in which plasma sodium is falsely low as measured by conventional methods in spite of the fact that it is not actually low. This may occur when large molecules are at a high concentration at an abnormally high level and, consequently, when the plasma water ratio falls abnormally. It has been reported that associated hyperlipemia and hyperproteinemia can also be seen in patients with diabetes mellitus. Real values can be obtained by evaluating the concentration based on plasma/water ratio.

Excessive administration of potassium-free solutions may result in significant hypokalemia. Serum potassium levels should be maintained and potassium supplemented as required.

To minimize the risk of possible incompatibilities arising from mixing any of these solutions with other additives that may be prescribed, the final mixture should be inspected for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

If administration is controlled by a pumping device, care must be taken to discontinue

pumping action before the container runs dry or air embolism may result.

This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact. Laboratory tests:

Clinical evaluation and periodic laboratory determinations 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. Significant deviations from normal concentrations may require normalization of these values with alternative solutions.

Warnings and precautions for pediatric use:

In neonates or in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially preterm neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

Warnings and precautions for use in elderly:

In general, dose selection for an elderly patient should be cautious. Starting at the low end of the dosing range is recommended in elderly considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Interaction with other medicinal products and other forms of interaction Some of the drugs and solutions added to the solution may be incompatible. As in all parenteral solutions, compatibility with additional medication should be evaluated by the physician.

If other substances are to be added to the solution, aseptic technique should be used and shaken until mixed. It should be ensured that there is no discoloration, insoluble particles and crystallization after the drugs are added into TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE.

Caution should be exercised because of the risk of sodium and water retention when used with corticosteroids and carbenoxolone due to its sodium content.

Special populations:

No interaction studies have been performed with TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE on special population.

Pediatric population:

No interaction studies have been performed with TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE in the pediatric population.

General recommendation

Pregnancy category: C

Women with childbearing potential/Contraception

No effects of TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE on women of childbearing potential or interaction with drugs used for birth control (contraception) have been reported.

Pregnancy

There are no adequate data from the use of isotonic sodium chloride solutions in pregnant women.

Studies on animals are insufficient in terms of effects on pregnancy / and - or /

embryonal / fetal development / and - or / birth / and - or postnatal development. (See section 5.3). Potential risk for human is unknown.

TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE should not be used during pregnancy unless it is necessary for life-threatening conditions.

Animal reproduction studies have not been conducted with sodium chloride containing solutions.

It is also not known whether TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE should be given to a pregnant woman only if clearly needed.

Delivery:

The effects of TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of thenewborn will be necessary, and on the later growth, development, and functional maturation of the child are unknown.

Administration of sodium and dextrose containing solutions during labor and delivery have been reported in the literature. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

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 TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is administered to a nursing woman.

There are no data on the effects of sodium chloride solutions on fertility.

Undesirable effects are not expected in normal conditions of treatment. Undesirable effects may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential. The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted. Injudicious intravenous sodium chloride therapy (e.g. postoperatively and in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shifts decrease intracellular volume, resulting in dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage.

If administered sub-cutaneously, any addition to the isotonic solution could render it hypertonic and cause pain at the site of injection.

Administration of large doses may give rise to sodium accumulation, oedema, and hyperchloraemic acidosis.

If an adverse reaction does occur during administration, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures. The displayed frequency categories use the following convention: Very common (\geq 1/10); common (\geq 1/100 to < 1/10); uncommon (\geq 1/1,000 to < 1/100); rare (\geq 1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated form the available data). The following adverse reactions are those that may result in an excess of sodium or chloride due to overdose, or may be due to administration technique. The frequency of these side effects is not known (it can be seen in as few patients as cannot be identified with the available data). Blood and lymphatic system disorders

Not known: Thrombosis; hemorrhage

Metabolism and nutrition disorders

Not known: Sodium accumulation; Water retention and edema; Exacerbation of

congestive heart failure (due to hypernatremia); Hyperchloremic acidosis.

Nervous system disorders

Not known: Headache, dizziness, restlessness, irritation, convulsions, coma and death (dehydration of the brain associated with hypernatremia).

Cardiac disorders

Not known: Tachycardia (associated with hypernatremia).

Vascular disorders

Not known: Hypertension (associated with hypernatremia).

Respiratory, thoracic and mediastinal disorders

Not known: Pulmonary edema, respiratory depression and respiratory arrest

(associated with hypernatremia).

Gastrointestinal disorders

Not known: Nausea, vomiting, diarrhea, abdominal cramps, feeling of thirst, decreased salivation (associated with hypernatremia).

Skin and subcutaneous tissue disorders

Not known: Decreased perspiration (associated with hypernatremia).

Musculoskeletal and connective tissue disorders

Not known: Muscle twitching and rigidity (associated with hypernatremia).

Renal and urinary disorders

Not known: Renal failure (associated with hypernatremia)

General disorders and administration site conditions

Not known: Fever; Fatigue (due to hypernatremia); Pain at the injection site (due to subcutaneous administration of hypertonic solution with additions).

Surgical and medical procedures

Not known: Febrile reactions; infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection; extravasation and hypervolemia (adverse effects that can be seen due to the technique of administration).

Adverse reactions of sodium excess in the body include nausea, vomiting, diarrhea, abdominal cramps, thirst, reduced salivation, lacrimation and sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, fatigue, muscular twitching and rigidity, convulsions, coma, and death.

Excess chloride accumulation in the body may cause a loss of bicarbonate with an acidifying effect on body fluids.

In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

Diuretics may be used in the treatment of oedema associated with isotonic expansion and appropriate replacement therapy which will not cause fluid electrolyte imbalance should be applied.

Treatment of hypervolemic hypernatremia requires removal of more sodium than water from the body and diuretic-induced sodium and water loss can only be met by water. The main purpose of the treatment is to normalize the volume and composition of body fluids.

When overdose is related to medicinal products 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.

Pharmacotherapeutic group: Intravenous solutions/Solutions affecting electrolyte balance

ATC code: B05XA03

TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE 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, cardiac electrophysiology and in renal metabolism. Chloride is mainly an extracellular anion. Intracellular chloride is in high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

The pharmacodynamic properties of the added drugs are the same as the pharmacodynamic properties of the added drug.

General properties

Pharmacokinetic properties of TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE are those of its components (sodium and chloride).

Absorption:

Active substances in drugs administered intravenously reach their maximum plasma concentrations immediately after administration.

Distribution:

Sodium distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurons; it is very slow in the bone. Chloride is mainly distributed in extracellular fluids.

Biotransformation:

The half-life after radioactively labeled sodium (24Na) injection is 11-13 days for 99% of injected sodium and one year for the remaining 1%.

Chloride closely monitors sodium metabolism and changes in the acid-base balance of the body are reflected by changes in chloride concentration. Elimination:

Sodium is excreted primarily by the renal route, but at the same time the vast majority is reabsorbed by the renal route. A small amount of sodium is excreted with feces and sweat.

Since chloride metabolically monitors sodium, it is mainly excreted by the renal route but also in lesser amounts in feces and sweat.

Linearity/Non-linearity:

Electrolytes in the TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE composition show a linear pharmacokinetic behavior when administered to the body at therapeutic doses to complete their deficiency.

Because the components of the solution are physiological components of human and animal plasma and are not expected to show toxic effects in clinical practice, studies with TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE have not been performed to evaluate the effects of carcinogenic, mutagenic potential and fertility. The safety of medications added into the solution must be considered separately.

Incompatibilities

Incompatibility of the medicinal product to be added with the solution must be assessed before addition. In the absence of compatibility data, this solution must not be mixed with other medicinal products.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the solution by checking for eventual color change and/or eventual precipitate, insoluble complexes or crystals apparition. The prescribing information of the drug to be added to TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE must be consulted to decide whether the additive is compatible.

Before adding a drug, its solubility and stability at the pH of TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE should be verified.

TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE should be immediately used following the addition of a compatible drug.

Those additives known to be incompatible should not be used.

6.3. Shelf life

36 months.

Shelf life during use for dilution:

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

6.4. Special precautions for storage

There are no special conditions for storage. It must be kept at room temperature under 30 °C.

6.5. Nature and contents of container

50, 100, 150, 250, 500, 1000 and 3000 ml PP (polypropylene) bags

Product has in two forms: with and without set.

Directions for use

Solution should be inspected visually before use.

The administration is by intravenous route with sterile sets.

Only products that are clear, particle-free and intact in packaging integrity should be used.

The administration should be started as soon as possible after the application set is attached to the product.

In order to prevent an air embolisation that may occur due to the residual air in the bag, no serial connection should be made with other infusion fluids.

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.

The solution should be applied using the aseptic technique through the sterile application set. In order to prevent air from entering the system, liquid must be passed through the application set before use.

Additional medication may be added before and during infusion with the aid of injection a needle in aseptic conditions. The final product's isotonicity should be determined before parenteral administration.

The added drug must be completely mixed with the solution before application to the patient. 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. For single use.

Do not store partially used solutions.

Do not reconnect partially used bags.

To open:

1. Check the integrity of the outer packaging and check for leaks; do not use if the packaging is damaged.

2. Tear off the protective outer packaging.

3. Check for minute leaks by squeezing inner bag firmly. Check solution for limpidity and absence of foreign matter.

Preparation for administration:

- 1. Suspend the bag.
- 2. Remove the protector from application port.

3. Stick the spike of the application set firmly in the application tip.

4. The instructions for use of the set must be followed for the administration of the solution.

Addition of additional drug:

Attention: As with all parenteral solutions, all substances to be added to the product must be compatible with the product. If an addition is to be made, compatibility should be checked in the final mixture before administration to the patient.

Adding medication before administration

1. Disinfect medication site.

2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

3. Mix the solution and the added drug thoroughly. For high density medication such as potassium chloride, tap gently to the ports of the bag, while ports are upright to allow mixing.

Attention: Do not store bags containing added medications.

Adding medication during administration

- 1. Close the clamp.
- 2. Disinfect medication site.
- 3. Inject the drug to be added using syringe with 19 to 22 gauge needle.
- 4. Remove container from IV pole and/or turn to an upright position.
- 5. In this position, tap gently both ports to allow mixing of solution and medication.
- 6. Return bag to its former position and open the clamp and continue administration.

April 02, 2025

Subject: Temporary importation of 0.9% Isotonic Sodium Chloride Injection from Turk Ilac located in Ankara-TURKEY to address drug shortages per https://dps.fda.gov/drugshortages/activeingredient/sodium-chloride-09--injection

To prevent a shortage of large volume parenteral fluid drug products, Turk Ilac ve Serum Sanayi is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Isotonic Sodium Chloride Injection (50ml, 100ml, 150ml, 250ml, 500ml, 1000 ml, and 3000ml) from Turk Ilac ve Serum Sanayi manufacturing facility located in Ankara/TURKEY. FDA has not approved these products manufactured by Turk Ilac ve Serum Sanayi.

Effective immediately, and during this temporary period, Turk Ilac ve Serum Sanayi will offer the following imported product from Turk Ilac ve Serum Sanayi facility located in Ankara/TURKEY:

Product Name and Description	Volume	Bags per Box	NDC Code
Turkfleks %0.9 Isotonic Sodium Chloride	50ml	100	85160-400-10
Turkfleks %0.9 Isotonic Sodium Chloride	100ml	50	85160-400-20
Turkfleks %0.9 Isotonic Sodium Chloride	150ml	50	85160-400-30
Turkfleks %0.9 Isotonic Sodium Chloride	250ml	25	85160-400-40
Turkfleks %0.9 Isotonic Sodium Chloride	500ml	20	85160-400-50
Turkfleks %0.9 Isotonic Sodium Chloride	1000m	20	85160-400-60
Turkfleks %0.9 Isotonic Sodium Chloride	3000m	10	85160-400-70

Please note the following:

- Upon receiving Submission Acceptance Turk Ilac ve Serum Sanayi will have bag labels written in both Turkish and English.
- The bag labels will contain the active pharmaceutical ingredient, concentration, volume, and NDC code in English.
- The imported products' administration port system is fully compatible with sets marketed in the United States.
- The imported products use a carton box that is taped closed. To avoid damage to the solution container, take care not to use sharp instruments to open the box.
- The imported products do not contain barcodes on the unit label. Alternative
 procedures should be followed to ensure that the correct drug product is being used
 in all systems and processes and administered to individual patients. For example,
 institutions should consider manually inputting the product into their systems and
 confirm that barcode systems do not provide incorrect information when the
 product is scanned.
- 0.9% Isotonic Sodium Chloride Injection is available only by prescription in the United States. However, the imported products do not have the statement "Rx only" on the labeling.
- USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG CONTAINS A LEAK.

Additional key differences in the labeling between the FDA-approved product and the imported products are stated in the product comparison table at the end of this letter as follows:

Table 1. Key differences between FDA-approved and Turkfleks 0.9% Isotonic Sodium Chloride Injection

Table 2. Label images of FDA-approved and Turkfleks 0.9% Isotonic Sodium Chloride Injection

Reporting Adverse Events or Product Quality Issues

To report adverse events associated with these imported products, please use the contact us at info@turkilac.com.tr.

Adverse events or quality problems experienced with the use of these imported products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm

or call 1-800332-1088 to request a reporting form, then complete and return to the address on the preaddressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Sincerely,

Mehmet Berat Battal

Table 1: Key Differences between FDA Approved product and Turkfleks %0.9 Isotonic Sodium Chloride

	FDA- Approved Product	Turkfleks Import from Turkey
Product Name	0.9% Sodium Chloride injection USP*	%0.9 Isotonic Sodium Chloride Injection
Label Volume	50 mL, 100 mL, 150 mL, 250 mL, 500 mL, 1000 mL	50 mL, 100 mL, 150 mL, 250 mL, 500 mL, 1000 mL, 3000 mL
Language of the Labels	English	Turkish
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride. Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	Source of water for electrolytes and: - In the treatment of isotonic extracellular dehydration - In the treatment of sodium losses - As a diluent solution for drugs with which it is compatible in parenteral applications
Active Ingredients	Each 100 ml contains 0.9g Sodium Chloride, USP	Each 100 ml contains 9g Sodium Chloride
Additional Information	pH is 5.6 (4.5-7.0) Osmolarity 310 mOsm/L (calc)	pH is 5.5 (4.5-7.0) Osmolarity 308 mOsm/L (calc)
Store Conditions	Store at room temperature 25C/77F	Store at below 30C
Container Type	ethylene and propylene	Polypropylene

*Description states: Sodium Chloride Injections USP are sterile, nonpyrogenic, isotonic and contain no bacteriostatic or antimicrobial agents.

Table 2: Label Images of FDA-approved and Turkfleks %0.9 Isotonic Sodium Chloride Injection



% 0,9 İ % 0,9 İ Sodyum Çöze	^{TURKFLEKS®} zotonik Klorür Itisi
500 mL	STERIL I.V. INFÜZYON
Her 100 mL çözeltide : Sodyum Klorür Enjeksiyonluk Su Elektrolit Konsantrasyonları Sodyum Klorür Total Osmolar Konsantrasyor	: 900 mg : k.m. içerir. mEq/L (mmol/L) : 154 (154) : 154 (154) : 308 mOsm/L
ASEPTİK OLARAK Çözelti berrak değils veya torba zedelenm Kullanmadan önce okuyunuz. Beklenmeyen doktorunuza başvurunuz. torbada kalan çözeltiy 30°C'nin altındaki oda ışık almayan bir yerda göremeyeceği, erişeme ambalajında saklayınız. ambalajıları satın almayır	DAMARA VERİLİR. e, partikül içeriyorsa iş ise kullanmayınız. Kullanma Talimatını bir etki görüldüğünde Uygulamadan sonra i tekrar kullanmayınız. sıcaklığında, doğrudan e saklayınız. Çocukların yeceği yerlerde ve Kesilmiş veya açılmış nız. Reçete ile satılır.
Ruhsat Numarası Ruhsat Sahibi ve Üretim Yeri TURK İlaç ve Serum Sanayi 06750 Akyurt / ANKARA Tel : 0(312) 837 67 67 E-posta : info@turkilac.com.	: 16/02/2015 - 2015/160 : A.Ş.

Т	TURKFLEKS 0.9% ISOTONIC SODIUM CHLORIDE SOLUTION					
0.	0.9% isotonic sodium chloride solution injection, solution					
P	Product Inf	formation				
P	roduct Type	•	HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:85160-400
R	oute of Adn	ninistration	INTRAVENOUS			
	Active Ingredient/Active Moiety					
Ingredient Name F			Basis of Strength	n Strength		
CHLORIDE ION (UNII: Q32ZN48698) (CHLORIDE ION - UNII:Q32ZN48698) CHLORIDE ION 0.9 g in 100 m					0.9 g in 100 mL	
P	Packaging					
#	ltem Code		Package Description		Marketing Start Date	Marketing End Date
1	NDC:85160- 400-10	100 in 1 BOX			01/15/2025	
1	NDC:85160- 400-01	50 mL in 1 BAG; T Device/System (sy	ype 2: Prefilled Drug Delivery rringe, patch, etc.)			
2	NDC:85160- 400-20	50 in 1 BOX			01/15/2025	
2	NDC:85160- 400-02	100 mL in 1 BAG; Device/System (sy	Type 2: Prefilled Drug Delivery rringe, patch, etc.)			
3	NDC:85160- 400-30	50 in 1 BOX			01/15/2025	

3	NDC:85160- 400-03	150 mL in 1 BAG Device/System (s	Type 2: Prefilled Drug Delivyringe, patch, etc.)	very		
4	NDC:85160- 400-40	25 in 1 BOX		01/15/2025		
4	NDC:85160- 400-04	250 mL in 1 BAG Device/System (s	250 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)			
5	NDC:85160- 400-50	20 in 1 BOX		01/15/2025		
5	NDC:85160- 400-05	500 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)				
6	NDC:85160- 400-60	20 in 1 BOX		01/15/2025		
6	NDC:85160- 400-06	1000 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)				
7	NDC:85160- 400-70	10 in 1 BOX		01/15/2025		
7	NDC:85160- 400-07	3000 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)				
Marketing Information						
	Marketing	g Category	Application Num Monograph Cita	ber or ation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		g for use in drug		C)1/15/2025	

Labeler - TURK ILAC VE SERUM SANAYI (533104534)

Registrant - TURK ILAC VE SERUM SANAYI (533104534)

Establishment

Name	Address	ID/FEI	Business Operations
TURK ILAC VE SERUM SANAYI		533104534	manufacture(85160-400)

Revised: 4/2025

TURK ILAC VE SERUM SANAYI