POLIFLEKS- 0.9% isotonic sodium chloride solution
POLIFARMA ILAC SANAYI VE TICARET ANONIM SIRKETI CORLU SUBESI

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.

[Text Box: Subject: Temporary Importation of 0.9% Sodium Chloride Injection Products from Turkey to address drug shortages.] February 21, 2025

Dear Healthcare Provider,

In order to address shortages of Sodium Chloride Injection, USP, in the United States, GLOBAL GUARD INC. is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Solution from POLIFARMA's manufacturing facility in Turkey.

FDA has not approved these products manufactured by Polifarma.

You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because as each letter may contain different product-specific information.

At this time, no other entity except Global Guard, Inc is authorized by the FDA to import or to distribute this Polifarma product in the United States.

Effective immediately, and during this temporary period, Global Guard, Inc., will offer the following presentations of Polifarma POLİFLEKS® 0.9% Isotonic Sodium Chloride Solution:

Product name and Description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection (POLİFLEKS®)	50mL	84879-263	100	84879-263-01
0.9% Sodium Chloride Injection (POLİFLEKS®)	250mL	84879-263	40	84879-263-02
0.9% Sodium Chloride Injection (POLİFLEKS®)	500mL	84879-263	25	84879-263-03
0.9% Sodium Chloride Injection (POLİFLEKS®)	1000mL	84879-263	15	84879-263-04
0.9% Sodium Chloride Injection (POLİFLEKS®)	3000mL	84879-263	5	84879-263-05

It is important to note the following:

The imported products do not have a UPC barcode on the bag, rather they have a GTIN barcode that contains the product Global Trade Identification Number (GTIN). The barcode on the imported product labels may not register accurately in U.S. scanning systems. 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 ensure that barcode systems provide correct information when the

product is scanned.

These products are available only by prescription in the U.S. the imported products do not have the statement “Rx only” they state Sold with Prescription on the labeling.

After opening the carton or box, the bags should be inspected visually to confirm there is no visible particulate matter or bag defects; such as, leaks. Container integrity is imperative to ensure sterility of products listed in Table 1. Parenteral drug products should be inspected visually for particulate matter and bag defects prior to administrations, whenever solution or container permits. This requirement is specifically stated on the package for the products which are subject to this notification.

You should perform a visual inspection of the bag prior to administration of the solution.

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 products and the imported products are stated in the product comparison tables at the end of this letter as follows:

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

Please refer to FDA-approved prescribing information as follows:

0.9% Sodium Chloride Injection, USP, Polifleks Polypropylene I.V. bag (click here)

Reporting Adverse Events:

Healthcare providers should report adverse events associated with the use of POLİFLEKS 0.9% Isotonic Sodium Chloride Solution for I.V. Infusion to GLOBAL GUARD LLC by phone: 1-800-555-1212 NEED TO ESTABLISH # ; email: AER@GLOBALGUARDCORP.COM NEED TO ESTABLISH

Adverse reactions or quality problems experienced with the use of this product may 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 https://www.accessdata.fda.gov/scripts/medwatch/index.cfm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Please ensure that your staff and others in your institution who may be involved in the administration of POLİFLEKS 0.9% Isotonic Sodium Chloride Solution for I.V. Infusion receives a copy of this letter and reviews the information.

To place an order:

please contact GLOBAL GUARD LLC at orders@globalguardcorp.com

For all other inquiries please contact GLOBAL GUARD LLC at 1-800-555-1212 (phone); email: INFO@GLOBALGUARDCORP.COM

Gürmen Kaynar Michael Bogdan

International Markets and President
Business Development Director Global Guard LLC
POLIFARMA İLAC SAN. ve TIC. A.Ş.

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

FDA approved product

Imported product from Turkey

Product name

Sodium Chloride Injection, USP

in VIAFLEX Plastic Container

POLİFLEKS 0.9% Isotonic Sodium Chloride Solution for I.V. Infusion

Label volume

1,000 mL

1,000 mL

Language of the labels

English

English

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.

POLİFLEKS 0.9% ISOTONIC SODIUM CHLORIDE is indicated in the following situations:

- Treatment of isotonic extracellular dehydration

- Treatment of sodium depletion

- As diluent of compatible drugs for parenteral administration.

Active Ingredients

Each 100 ml contains 900 mg Sodium Chloride, USP

Each 100 ml contains 900 mg Sodium Chloride

Additional Information

pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)

pH is 5.5 (4.5 – 7.0). Osmolarity of solution is 308 mOsmol/l.

Storage conditions

Store at room temperature 25 ° C/77° F.

Store at room temperature below 25°C.

Container type

VIAFLEX PVC

POLIFLEKS POLYPROPYLENE

Medication and administration port closures

Contains medication port and administration port; Pull off port protector (blue color), right side

Contains medication port and administration port; Pull off port protector (CLEAR/no color), right side

[A close-up of a plastic tube Description generated with high confidence]

Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injections

FDA approved product

Imported product from Turkey

0.9% Sodium Chloride Injection USP

0.9% ISOTONIC SODIUM CHLORIDE SOLUTION

Label Color: Black barcode not shown

1,000 mL shown as representative label

Label: Color Black barcode shown 1000 mL shown as representative label

Sodium: 154 mEq= 154 mmol
Chloride: 154 mEq= 154 mmol
Total Osmolar Concentration: 308 mOsm/L
Marketing Authorization Holder and
Manufacturing Site:
Polifarma İlaç San. ve Tic. A.Ş.
Ergene/Tekirdağ
e-posta: info@polifarma.com.tr
® Registered Trademark

SOLUTION FOR I.V. INFUSION
STERILE - I.V. INFUSION

8 699606 693291

information leaflet before use. Store at room temperature below 25°C. Consult your physician in case of any unexpected side effect. Do not use the remaining solution after administration. Keep out of reach and sight of children and store in package. Do not buy cut or openned packages.
Sold with prescription.

POLİFLEKS® 3000 ml

POLİFARMA

Polifleks

750

0.9 % ISOTONIC SODIUM CHLORIDE

SOLUTION FOR I.V. INFUSION

STERILE - I.V. INFUSION

1500

100 ml;

Sodium Chloride	: 0.9 g
Water for Injection q.s.	: 100 ml

Electrolyte Concentrations (mEq/L) :
Sodium : 154 Chloride : 154
Total Osmolar Concentration: 308 mOsm/L
See patient information leaflet for additional information.

2250

ADMINISTERED ASEPTICALLY BY INTRAVENOUS INJECTION.

Do not use if the solution is not clear, contains particles or the container is not intact. Read patient information leaflet before use. Store at room temperature below 25°C. Consult your physician in case of any unexpected side effect. Do not use the remaining solution after administration. Keep out of reach and sight of children and store in package. Do not buy cut or openned packages.

2750

Sold with prescription.

Manufactured by:
Polifarma İlaç San. ve Tic. A.Ş.
Ergene / Tekirdağ / Turkey
e-mail: info@polifarma.com.tr
® Registered Trademark

3 PVC

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POLIFLEKS

0.9% isotonic sodium chloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:84879-263
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOTONIC SODIUM CHLORIDE SOLUTION (UNII: VR5Y7PDT5W) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CATION	0.9 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84879-263-01	50 mL in 1 BAG; Type 0: Not a Combination Product	03/10/2025	
2	NDC:84879-263-02	250 mL in 1 BAG; Type 0: Not a Combination Product	03/10/2025	
3	NDC:84879-263-03	500 mL in 1 BAG; Type 0: Not a Combination Product	03/10/2025	
4	NDC:84879-263-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	03/10/2025	
5	NDC:84879-263-05	3000 mL in 1 BAG; Type 0: Not a Combination Product	03/10/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		03/10/2025	

Labeler - POLIFARMA ILAC SANAYI VE TICARET ANONIM SIRKETI CORLU SUBESI (751139942)

Establishment

Name	Address	ID/FEI	Business Operations
POLIFARMA ILAC SANAYI VE TICARET ANONIM SIRKETI CORLU SUBESI		751139942	analysis(84879-263) , label(84879-263) , manufacture(84879-263) , pack(84879-263) , sterilize(84879-263)

Revised: 3/2025 POLIFARMA ILAC SANAYI VE TICARET ANONIM SIRKETI CORLU SUBESI