

SODIUM CHLORIDE INJECTION, SOLUTION- sodium chloride injection injection HK INNO.N CORPORATION

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.

INDICATIONS & USAGE

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.

Storage: Store at room temperature 20°C/68°F. to 25°C/77°F.

Medication Administration: Contains medication port and administration port; Twist off shield, left side

These highlights do not include all the information needed to use Sodium Chloride 0.9% Injection. See full prescribing information for Chloride 0.9% Injection. This product is an unapproved product for use in urgent drug shortage” (code C101533).

INSTRUCTIONS FOR USE

Contains medication port and administration port; Twist off shield, left side

inno.N

Safe-Flex[®] 전문의약품

0.9%NS

0.9% Normal Saline Inj.
STERILE & PYROGEN-FREE

1000mL

이노엔0.9%생리식염주사액

- 원료약품 및 그 분량 이 약 1000밀리리터 중
유효성분 염화나트륨(KP) 9.0그램
용제 주사용수(KP) 적당
- **성상** 외부를 반투명의 고밀도 폴리에틸렌으로 포장한
무색투명한 수액용 플라스틱용기에 충전된
무색투명한 수액용 주사제
- **효능·효과, 용법·용량, 주의사항** 첨부문서 참조
- **저장방법** 일불용기, 실온보관(1~30℃)

⚠️ 육안으로 보이는 이물이 있거나 손상된 제품은 사용하지 마십시오.

제조사 **에이치케이이노엔주식회사**
충청북도 청주시 흥덕구 오송읍 오송생명2로 239
<http://www.inno-n.com>



OTHER
재활용 어려움

제조번호

사용기한

DHCP Letter for unapproved product for use in urgent drug shortage” (code C101533)

November 22, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection from South Korea to address drug shortages

Dear Healthcare Professional,

To prevent a shortage of large volume parenteral fluid drug products, Supply Line International Medical (SLI Medical) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection (1,000 mL) from Inno.N's manufacturing facility in South Korea. FDA has not approved these products manufactured by Inno.N's South Korea facility.

At this time, no other entity except SLI Medical is authorized by the FDA to import or to distribute this Inno.N product in the United States.

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

Effective immediately, and during this temporary period, Supply Line International Medical LLC will offer the following imported product from Inno.N's facility in South Korea:

Product Overview:

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	1,000ml	171440	10	84988-1440-01

Approved Lots

Lot Number	Manufacturing date	Expiry date
NS624K4	2024.09.25	2026.03.24
NS624K5	2024.10.02	2026.04.01
NS624H8	2024.08.13	2026.02.12
NS624H9	2024.08.13	2026.02.12
NS624J0	2024.08.21	2026.08.21
NS624J1	2024.08.22	2026.08.22
NS624J2	2024.08.22	2026.08.22
NS624J3	2024.08.29	2026.08.29
NS624J4	2024.08.29	2026.08.29

It is important to note the following:

- The imported products have primary container labels written in both Korean and English. The primary container labels contain the active pharmaceutical ingredient, concentration, volume, and product code in English.
- The imported products' administration port system is fully compatible with sets marketed in the United States.

inno.N

Safe-Flex[®]

Prescription drugs

0.9%NS

0.9% Normal Saline Inj.
STERILE & PYROGEN-FREE

1000mL

Innoen 0.9% saline injection

• Raw materials and their quantities are about 1000 milliliters

Active ingredient: Sodium chloride (KP)	9.0 grams
Solvent injection water (KP)	-----

• A colorless transparent injection for intravenous fluid filled in a colorless transparent plastic container for intravenous fluid with a translucent high-density polyethylene exterior

• Please refer to the attached document for efficacy effects, usage dosage, and precautions.

• Storage method: Sealed container, store at room temperature (1-30°C)

▲ Do not use products that contain visible foreign substances or are damaged.

Manufacturer: HKINNOEN Co., Ltd.

231 Osong-Lib 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do

<http://www.inno-n.com>



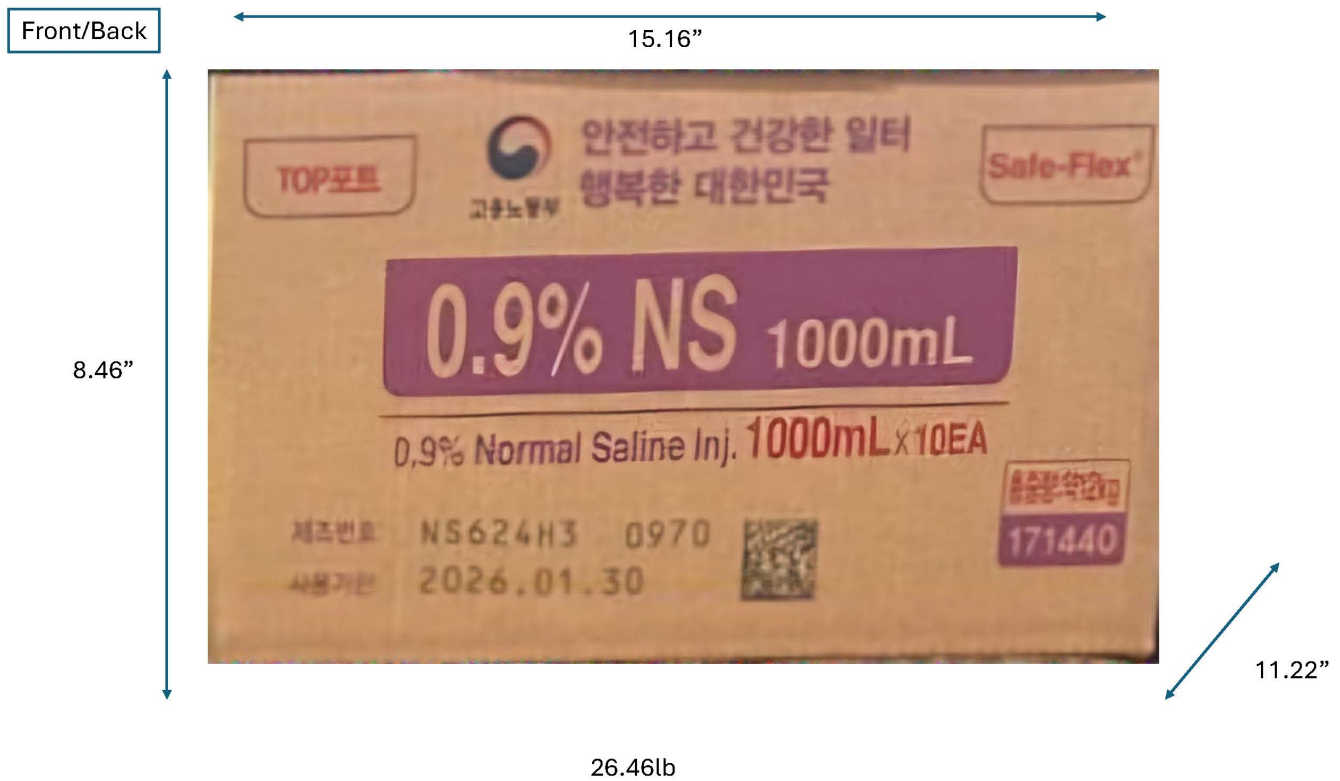
171440001

OTHER Recycling
Difficulties

Manufacturing number

Expiration date

Inno,N Box Images



SODIUM CHLORIDE INJECTION, SOLUTION

sodium chloride injection injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84988-1440
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84988-1440-1	1000 mL in 1 BAG; Type 0: Not a Combination Product	11/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/26/2024	

Labeler - HK INNO.N CORPORATION (689049556)

Registrant - HK INNO.N CORPORATION (689049556)

Establishment

Name	Address	ID/FEI	Business Operations
HK INNO.N CORPORATION		689049556	manufacture(84988-1440)

Revised: 11/2024

HK INNO.N CORPORATION