Baxter

Temporary Importation of Injection Solutions from Shanghai (1.1)

In order to address shortages of critical drug products from the aftermath of Hurricane Helene, Baxter is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection, 5% Glucose Injection, 10% Glucose Injection, and 5% Glucose and 0.9% Sodium Chloride Injection from Baxter's manufacturing facility in Shanghai, China. FDA has not approved these products manufactured by Baxter's Shanghai facility.

The information contained in this letter pertains only to the products listed below.[1]

For additional information, please refer to the Important Prescribing Information

Temporary importation of Baxter products from Shanghai, China, labeled in English.

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	250 mL	A6C1322US	40	0338-9791-01
	500 mL	A6C1323US	24	0338-9808-01
	1,000 mL	A6C1324US	12	0338-9793-01
5% Glucose Injection	250 mL	A6C0062US	40	0338-9795-01
	1,000 mL	A6C0064US	12	0338-9801-01
10% Glucose Injection	250 mL	A6C0162US	40	0338-9797-01
5% Glucose/0.9% Sodium Chloride Injection	1,000 mL	A6C1064US	12	0338-9799-01

Temporary importation of Baxter products from Shanghai, China, labeled in Mandarin.

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	250 mL	A6C1322	40	0338-9804-01
	500 mL	A6C1323	24	0338-9810-01
	1,000 mL	A6C1324	12	0338-9806-01

Material Composition

The table below lists the IVINA fluid path component materials only. The referenced products may contain additional materials not listed. However, these products are not made with natural rubber latex, Polyvinyl Chloride (PVC) or Di(2-ethylhexyl) phthalate (DEHP).

IVINA Material Composition	
Container/Bag Material	
Film	Polypropylene (PP), Styrene-ethylene-butylene copolymer (SEB), Polyethylene (PE)
Container Port Tubing Material	
Port Tubing	Polypropylene (PP), Ultra low-density polyethylene (ULDPE), Styrene-ethylene-butylene-styrene copolymer (SEBS), Polyamide (PA)
Medication Port Material	
Membrane Tubing	Polypropylene (PP), Styrene-ethylene-butylene-styrene copolymer (SEBS) and Polyamide (PA)
Membrane Film	Polypropylene (PP), Ultra low-density polyethylene (ULDPE), Styrene-ethylene-butylene-styrene copolymer (SEBS), Polyamide (PA)
Sleeve Stopper	Synthetic Polyisoprene
Administration Port Material	
Twist-off Protector	Polypropylene (PP), Ethylene-vinyl-acetate (EVA), Styrene-ethylene-butylene-styrene (SEBS)

Target Fill Volume, Fill Volume Range, and Maximum Additive Volume for Baxter Solutions in IVINA Single Pack Container

The table below lists the target fill volumes, fill volume ranges, and maximum additive volumes for Injection Solutions packaged in IVINA containers. If a specific volume of solution is required for a medication, it would be necessary to transfer the required volume of solution via a pump or syringe.

Container Labeled Volume (mL)	Target Fill Volume (mL)	Fill Volume Range (mL)	Maximum Additive Volume (mL)
250	272.5	263-281	80
500	531	519-543	100
1000	1040	1028-1052	100

Baxter Recommended Storage Condition

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature 15°C/59°F to 30°C/86°F.

Stability Out of Overwrap for Injection Solutions in IVINA Single Pack Plastic Containers

The table below lists the stability out of overwrap for Injection Solutions in IVINA Single Pack.

Container Labeled Volume (mL)	Stability Out of Overwrap
250 mL 500 mL 1000 mL	Up to 24 hours

Refrigerating Parameters for Injection Solutions in IVINA Single Pack Container
Although solutions for Injection are not tested at refrigerated storage temperatures (5°C), ICH Guidance considers the room temperature storage conditions to be the accelerated storage conditions for products intended for long-term storage under refrigeration (5°C ± 3°C), therefore existing room temperature data can be extrapolated to support storage of solutions under refrigeration. The table below lists the refrigerating parameters for Injection Solutions in IVINA Single Pack Container in the protective plastic overwrap (no impact on chemical stability).

Container Labeled Volume (mL)	Refrigerated Storage Parameters (Product remains in the overwrap)
250 mL 500 mL 1000 mL	Up to the expiry date printed on the individual container.

Recommended Use of the Medication Port on Baxter's IVINA Single Pack Container
The injection site of the medication port has a high self-sealing capacity and has been designed to withstand up to 8 punctures with an 18-gauge needle without leaking.

Administration Set Compatibility
The administration port on the IVINA Container was designed to conform with ISO8536-4.

For additional information, please go to Hurricane Helene Clinical Resources for US Healthcare Professionals (baxter.com)

This information is intended to provide pertinent data to assist you in forming your own conclusions and is not to be considered as medical advice. The information contained in this letter is applicable to products approved or cleared in the United States of America, unless specifically noted. Baxter does not advocate the use of its products outside of approved labeling. Please refer to Instructions for Use or Prescribing Information. This letter is provided as a service to Baxter customers, and it may not be reproduced without the prior written permission of Baxter Healthcare Corporation.

Reference:

1. Baxter internal data on file.