FRESENIUS KABI

URGENT DRUG RECALL

SECOND NOTICE – EXPANSION OF ONE (1) ADDITIONAL BATCH

December 3, 2018

Product Name/Product size	Unit of Sale NDC Number	Unit of Use NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial	63323-186-10	63323-186-01	918610	6013112	11/2018	02/06/2017	02/13/2017
				6013113	11/2018	02/13/2017	02/14/2017
				6013114	11/2018	02/14/2017	02/20/2017
				6013180	11/2018	02/10/2017	02/24/2017
				6013181	11/2018	02/17/2017	03/03/2017
				6013182	11/2018	02/27/2017	03/06/2017
				6013237	01/2019	03/01/2017	03/06/2017
				6013238	01/2019	03/03/2017	03/15/2017
				6013239	01/2019	03/08/2017	04/03/2017
				6013468	02/2019	03/27/2017	04/04/2017
				6013512	02/2019	04/03/2017	04/03/2017
				6013513	02/2019	04/03/2017	04/10/2017
				6013551	02/2019	03/20/2017	03/24/2017
				6013552	02/2019	03/22/2017	03/24/2017
				6013553	02/2019	03/23/2017	03/25/2017
				6013607	02/2019	04/06/2017	04/10/2017
				6013608	02/2019	04/10/2017	04/19/2017
				6013610	02/2019	04/13/2017	04/17/2017
				6013627	03/2019	04/17/2017	04/20/2017
				6013678	03/2019	04/20/2017	04/26/2017
				6013679	03/2019	04/24/2017	05/08/2017
				6013822	03/2019	06/16/2017	06/21/2017
				6013823	03/2019	06/15/2017	06/21/2017
				6013824	03/2019	06/19/2017	06/22/2017
				6013924	04/2019	05/04/2017	05/05/2017
				6013925	04/2019	05/04/2017	05/08/2017
				6013926	04/2019	05/05/2017	05/17/2017
				6014003	05/2019	06/22/2017	06/22/2017
				6014004	05/2019	06/22/2017	06/26/2017
				6014005	05/2019	06/26/2018	07/06/2017

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Product Name/Product size	Unit of Sale NDC Number	Unit of Use NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial	63323-186-10	63323-186-01	918610	6014260	05/2019	07/05/2017	07/07/2017
				6014301	05/2019	07/06/2017	07/07/2017
				6014302	05/2019	07/06/2017	07/07/2017
				6014303	06/2019	07/07/2017	07/18/2017
				6014304	06/2019	07/10/2017	07/17/2017
				6014305	06/2019	07/14/2017	07/27/2017
				6014306	06/2019	07/18/2017	07/20/2017
				6014307	06/2019	07/20/2017	07/24/2017
				6014384	06/2019	07/24/2017	07/31/2017
				6014404	06/2019	07/28/2017	08/07/2017
				6014405	06/2019	08/07/2017	08/14/2017
				6014453	06/2019	08/14/2017	08/21/2017
				6014454	06/2019	08/21/2017	08/25/2017
				6014455	06/2019	08/25/2017	08/31/2017
				6014479	06/2019	08/01/2017	09/14/2017
				6014557	07/2019	09/01/2017	09/06/2017
				6014558	07/2019	09/02/2017	09/27/2017
				6014606	07/2019	09/08/2017	09/15/2017
				6014649	08/2019	09/14/2017	09/18/2017
				6014650	08/2019	09/18/2017	10/17/2017
				6014704	08/2019	09/21/2017	09/25/2017
				6014766	08/2019	09/25/2017	10/02/2017
				6014767	08/2019	10/02/2017	10/09/2017
				6014768	08/2019	10/09/2017	10/26/2017
				6014841	08/2019	10/10/2017	10/14/2017
				6014842	08/2019	10/13/2017	10/16/2017
				6014843	08/2019	10/16/2017	11/01/2017
				6014861	08/2019	10/20/2017	10/23/2017
				6014862	08/2019	10/24/2017	11/13/2017
				6014863	08/2019	10/27/2017	11/07/2017
				6015049	09/2019	11/07/2017	11/13/2017
				6015050	09/2019	11/09/2017	11/10/2017
				6015088	09/2019	11/10/2017	11/20/2017

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Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial	63323-186-10	63323-186-01	918610	6015118	10/2019	11/20/2017	11/20/2017
				6015127	10/2019	11/17/2017	11/25/2017
				6015128	10/2019	11/20/2017	11/27/2017
				6015186	10/2019	11/21/2017	12/06/2017
				6015187	10/2019	11/22/2017	11/25/2017
				6015188	10/2019	11/25/2017	11/28/2017
				6015233	10/2019	11/27/2017	12/06/2017
				6015234	10/2019	11/30/2017	12/06/2017
				6015235	10/2019	01/02/2018	01/05/2018
				6015285	11/2019	12/05/2017	12/08/2017
				6015286	11/2019	12/08/2017	12/11/2017
				6015287	11/2019	12/11/2017	01/05/2018
				6015408	11/2019	01/04/2018	01/05/2018
				6015409	11/2019	01/04/2018	01/08/2018
				6015410	11/2019	01/05/2018	01/08/2018
				6015452	11/2019	01/08/2018	01/12/2018
				6015453	11/2019	01/08/2018	01/12/2018
				6015454	11/2019	01/10/2018	01/12/2018
				6015572	11/2019	01/11/2018	01/16/2018
				6015573	12/2019	01/15/2018	01/22/2018
				6015574	12/2019	01/16/2018	05/14/2018
				6015616	12/2019	01/16/2018	01/19/2018
				6015617	12/2019	01/18/2018	03/05/2018
				6015618	12/2019	01/18/2018	01/24/2018
				6015922	01/2020	02/23/2018	03/02/2018
				6015923	01/2020	02/28/2018	03/02/2018
				6015924	01/2020	03/02/2018	03/06/2018
				6016002	02/2020	03/06/2018	03/22/2018
				6016003	02/2020	03/08/2018	03/12/2018
				6016004	02/2020	03/10/2018	04/20/2018
				6016077	02/2020	04/20/2018	04/23/2018
				6016104	02/2020	04/23/2018	04/24/2018
				6016208	02/2020	03/29/2018	04/04/2018

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Product Name/Product size	Unit of Sale NDC Number	Unit of Use NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial	63323-186-10	63323-186-01	918610	6016209	02/2020	04/04/2018	04/06/2018
				6016210	02/2020	04/05/2018	04/09/2018
				6016258	02/2020	04/09/2018	04/09/2018
				6016259	02/2020	04/09/2018	04/11/2018
				6016260	02/2020	04/11/2018	04/12/2018
				6016261	02/2020	04/11/2018	04/12/2018
				6016262	03/2020	04/12/2018	04/12/2018
				6016263	03/2020	04/12/2018	04/13/2018
				6016264	03/2020	04/13/2018	04/23/2018
				6016323	03/2020	04/23/2018	04/23/2018
				6016324	03/2020	04/23/2018	04/24/2018
				6016325	03/2020	04/23/2018	04/24/2018
				6016383	03/2020	04/24/2018	04/25/2018
				6016384	03/2020	04/23/2018	04/25/2018
				6016385	03/2020	04/25/2018	04/27/2018
				6016386	03/2020	04/26/2018	04/26/2018
				6016387	03/2020	04/26/2018	04/30/2018
				6016388	03/2020	04/30/2018	05/09/2018
				6016389	03/2020	04/23/2018	05/09/2018
				6016584	04/2020	05/09/2018	05/16/2018
				6016585	04/2020	05/14/2018	05/17/2018
				6016621	04/2020	05/17/2018	05/19/2018
				6016622	04/2020	05/17/2018	06/04/2018
				6016623	04/2020	05/17/2018	05/17/2018
				6016765	05/2020	06/04/2018	06/11/2018
				6016766	05/2020	06/11/2018	06/13/2018
				6016767	05/2020	06/13/2018	06/16/2018
				6016768	05/2020	06/15/2018	06/20/2018
				6016769	05/2020	06/16/2018	07/10/2018
				6016875	06/2020	07/09/2018	07/11/2018
				6016876	06/2020	07/11/2018	07/13/2018
				6016877	06/2020	07/12/2018	07/13/2018
				6016878	06/2020	07/13/2018	08/13/2018

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Product Name/Product size	Unit of Sale NDC Number	Unit of Use NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial	63323-186-10	63323-186-01	918610	6016879	06/2020	07/16/2018	08/14/2018
				6017288	06/2020	08/13/2018	08/13/2018
				6017289	06/2020	08/13/2018	08/15/2018
				6017290	06/2020	08/13/2018	08/21/2018
				6017291	06/2020	08/16/2018	08/17/2018
				6017382	07/2020	08/16/2018	08/20/2018
				6017425	07/2020	08/17/2018	08/22/2018
				6017426	07/2020	08/17/2018	08/21/2018
				6017427	07/2020	08/21/2018	09/07/2018
				6017428	07/2020	08/20/2018	08/24/2018
				6017429	07/2020	08/20/2018	08/23/2018
				6017470	07/2020	08/23/2018	09/11/2018
				6017471	07/2020	09/07/2018	09/12/2018
				6017472	07/2020	08/27/2018	09/14/2018
				6017473	07/2020	09/13/2018	09/26/2018
				6017474	07/2020	09/11/2018	10/11/2018
				6017675	08/2020	10/11/2018	10/18/2018
				6017725	08/2020	10/19/2018	10/22/2018
				6017726	08/2020	10/15/2018	10/15/2018

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Product Name/Product size	Unit of Sale NDC Number	Unit of Use NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Sodium Chloride Injection, USP, 0.9%, 20 mL fill in a 20 mL vial	63323-186-20	63323-186-03	918620	6013062	11/2018	02/03/2017	06/21/2017
				6014162	05/2019	06/20/2017	07/10/2017
				6014163	05/2019	07/10/2017	12/05/2017
				6014164	05/2019	11/13/2017	11/28/2017
				6014377	06/2019	11/27/2017	12/06/2017
				6014378	06/2019	12/05/2017	12/13/2017
				6014379	06/2019	12/13/2017	03/19/2018
				6016005	02/2020	03/19/2018	03/20/2018
				6016071	02/2020	03/20/2018	03/22/2018
				6016072	02/2020	03/22/2018	03/30/2018
				6016073	02/2020	03/26/2018	04/02/2018
				6017383	07/2020	08/13/2018	08/16/2018
				6017384	07/2020	08/15/2018	08/17/2018
				6017422	07/2020	08/15/2018	08/27/2018
				6017423	07/2020	08/20/2018	09/04/2018
				6017424	07/2020	08/20/2018	09/11/2018

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Dear Customer/Healthcare Professional:

NOTE: This letter contains one (1) additional batch as noted above in yellow. The previously issued letter, dated 11/15/2018, did not include product code 918610, batch number 6017725. All other information contained within this letter remains unchanged.

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi"), formerly APP Pharmaceuticals, LLC, is voluntarily recalling the above-mentioned batches of Sodium Chloride Injection, USP, 0.9%, 10 mL fill in a 10 mL vial and Sodium Chloride Injection, USP, 0.9%, 20 mL fill in a 20 mL vial.

As a precautionary measure, this recall is being performed to the user level. Fresenius Kabi is taking this action due to an incorrect statement on the product insert for product codes 918610 and 918620 indicating that the stoppers do not contain natural rubber latex (Refer to Attachment 1). The tray label for these two product codes and the vial label for product code 918620 also incorrectly state that the stoppers do not contain latex (refer to Attachment 2). The above listed product codes and batches being recalled have stoppers containing natural rubber latex. The investigation reveals this issue is limited to the batches indicated above.

Fresenius Kabi USA has not received any reports of adverse events related to this recall. The risk of exposure to latex allergens in the drug product from these stoppers is low. Reactions to latex due to latex exposure from a latex-containing rubber stoppered vial are rare. If exposed, a reaction in susceptible individuals and for those with severe allergies could potentially be severe.

You are required to return all product from the above-mentioned batches that you have in your possession. To implement this recall, please do the following:

1. Examine your stock **immediately** to determine if you have any product vials from the affected batches. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product of this recall and direct them to quarantine and discontinue distributing or dispensing the affected batches. Please have them prepare to return the product to Fresenius Kabi (see enclosed information). Your customers may retrieve the recall letter and response form at https://www.fresenius-kabi.com/us/pharmaceutical-product-updates.

2. If you have the affected batches available, **immediately** quarantine and discontinue distributing, or dispensing any vials from the batches, and return all vials to Fresenius Kabi, USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106, via FedEx Ground, using the enclosed return goods label and packing slip. A FedEx Ground label can be obtained by checking the box and noting your mailing address on the enclosed Urgent Product Recall Response Form. It will be mailed to you upon receiving your request. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.

3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK IMMEDIATELY VIA EMAIL TO FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

CONTACT NUMBERS: Use the following contact phone numbers. Hours of operation: Monday through Friday 8:00 am to 5:00 pm CST

Number	Department	Reason to Call
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Event (ADE) reporting

This recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may cause you.

Sincerely,

Melanie Power-Burns
Vice President Quality Assurance

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APP

45764D /Revised: January 2008

SODIUM CHLORIDE
INJECTION, USP

0.9%

DESCRIPTION:
Sodium Chloride Injection, USP, 0.9% is a sterile, nonpyrogenic solution. The osmolarity is 300 mOsmol per liter (calculated).

Each mL contains: Sodium chloride 9 mg; Water for Injection q.s. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single dose containers. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment (pH 4.5-7.0).

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol.

The empirical formula for sodium chloride is NaCl and the molecular weight is 58.44.

CLINICAL PHARMACOLOGY:
Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9%, when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

latory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE:
Sodium Chloride Injection, USP, 0.9% preparations are indicated for diluting or dissolving drugs for intramuscular, intravenous or subcutaneous injection according to instructions of the manufacturer of the drug to be administered.

Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing of intravenous catheters.

WARNINGS:
For use in newborns, when a sodium chloride solution is required for preparation or diluting medications or in flushing intravenous catheters, only preservative free Sodium Chloride Injection, USP, 0.9% should be used.

PRECAUTIONS:
General
Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy
Pregnancy Category C—Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP, 0.9%. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP, 0.9% should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS:
Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and, if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE:
When used as a diluent, solvent or intravascular flushing solution, this parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures. (See **PRECAUTIONS** and **ADVERSE REACTIONS**).

DOSAGE AND ADMINISTRATION:
Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with sodium chloride.

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing intravenous catheters. Prior to and after administration of the medication, the intravenous catheter should be flushed in its entirety with Sodium Chloride Injection, USP, 0.9%. Use in accord with any warnings or precautions appropriate to the medication being administered.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED:
Sodium Chloride Injection, USP, 0.9%, preservative free, is available as follows:

Product No.	NDC No.	
918602	63323-196-02	2 mL in a 3 mL plastic vial
918610*	63323-196-10	In a 10 mL plastic vial
918620*	63323-196-20	In a 20 mL plastic vial

Single dose vials, packaged 25 vials per tray.

Preservative Free. Discard unused portion.

Use only if solution is clear and seal intact.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

*Vial stoppers do not contain natural rubber latex.

APP
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Schaumburg, IL 60173

45764D
Revised: January 2008

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Attachment 2

Image 1: Vial label for product code 918610 (does not contain latex free statement)

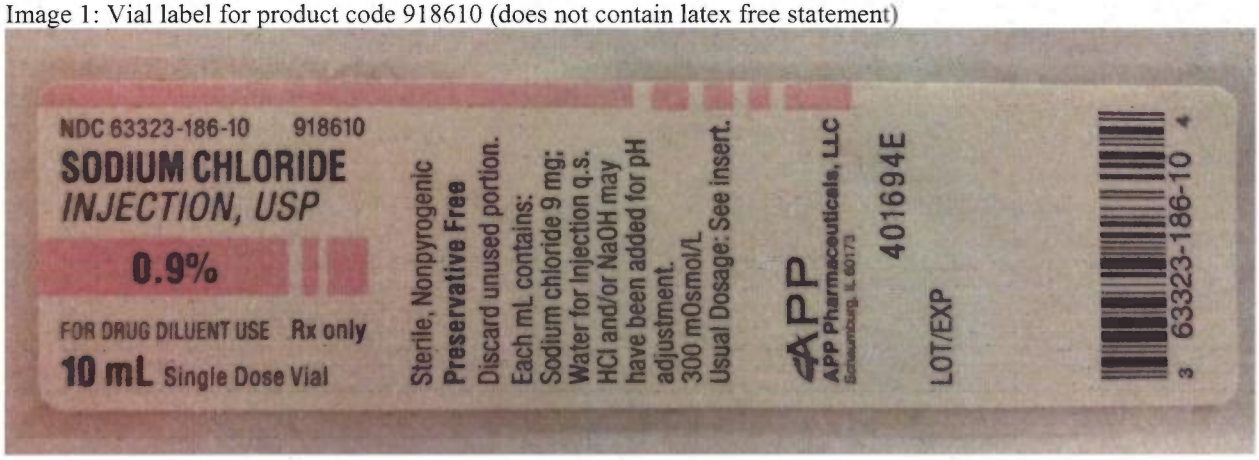
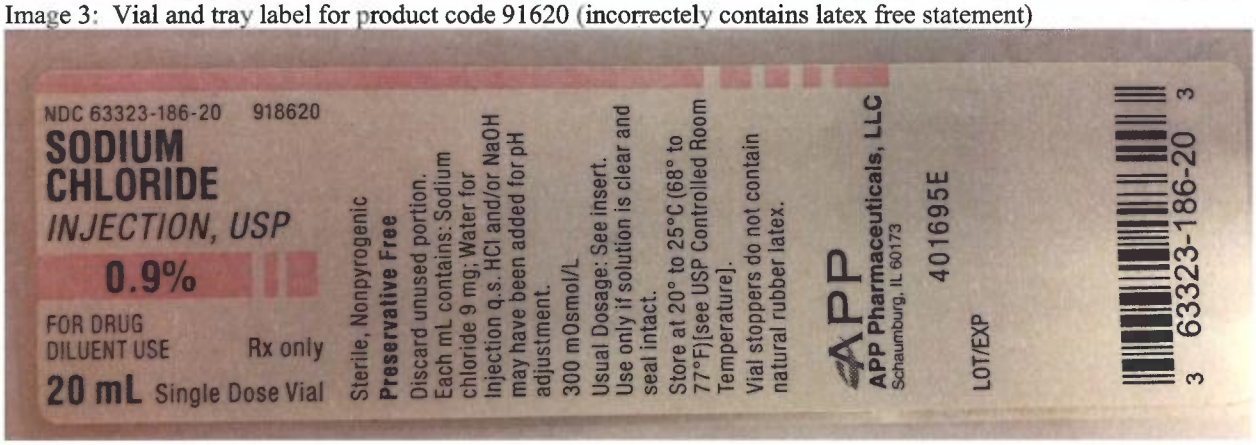


Image 2: Tray label for product code 918610 (incorrectly contains latex free statement)

Image 3: Vial and tray label for product code 91620 (incorrectely contains latex free statement)



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