

## Drug Shortage: Sodium chloride for injection

This document provides mitigation strategies for handling ongoing drug shortages to participants in the Vizient® Pharmacy Program. Information is compiled from mitigation strategies of institutions that serve on the Vizient Clinical Pharmacy Council and is reviewed by a panel of pharmacists. For more information, contact [pharmacyquestions@vizientinc.com](mailto:pharmacyquestions@vizientinc.com)

### Situation

This mitigation strategy is to serve as a resource if sodium chloride 0.9% for injection experiences supply disruptions due to a shortage.

### Background

Small volume sodium chloride 0.9% for injection is supplied in vials and prefilled syringes by multiple manufacturers. Previous shortages of sodium chloride 0.9% for injection have caused concern. This mitigation strategy is intended to provide guidance for present and future shortages.

#### Products affected<sup>a</sup>

|                                    |                                                                                                                                                                                                                                                                                                    |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sodium chloride 0.9% for injection | <ul style="list-style-type: none"> <li>10 mL single dose, preservative-free vial</li> <li>20 mL single dose, preservative-free vial</li> <li>50 mL single dose, preservative-free vial</li> <li>3 mL prefilled syringe</li> <li>5 mL prefilled syringe</li> <li>10 mL prefilled syringe</li> </ul> |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

<sup>a</sup>Review [ASHP Drug Shortages](#) for the most current information

### Assessment

Hospitals and health systems are advised to have a mitigation strategy available, to conserve inventory in the event of a shortage.

### Recommendation

#### Must know information

- Utilize sodium chloride 0.9% bags, sterile water for injection, or bacteriostatic sodium chloride 0.9% based on availability, or as able per medication package inserts or other clinical references.
- Actively review and evaluate the need for intravenous administration and encourage enteral route as clinically appropriate.
- Limit preparation of intravenous push medications on the floor to reduce wastage and conserve inventory.
- Reserve vials for areas where bags would not be ideal or feasible (eg, pre-packaged kits, crash carts).
- Reserve 10 mL prefilled saline syringes for flush and maintenance of central lines.
- Medefil supplies the only sodium chloride 0.9% 10 mL prefilled syringe FDA approved for dilution and reconstitution (NDC 64253-202-30).

### Clinical

- Utilize sodium chloride 0.9% bags, sterile water for injection, or bacteriostatic sodium chloride 0.9% based on availability, or as able per medication package inserts or other clinical references. See [Appendix 1](#) for differences in products.
- Actively review and evaluate the need for intravenous administration and encourage enteral route as clinically appropriate.
- Ensure preservative-free sodium chloride 0.9% is available for:

- Reconstitution of medications requiring preservative-free sodium chloride 0.9%
  - Preparation of ophthalmic products
  - Medications for neuraxial anesthesia or intrathecal chemotherapy
- 4) As clinically appropriate, advocate for removal of peripheral lines for conservation of prefilled saline syringes used for line flush and maintenance.

### Operational

- 1) Medefil supplies the only 10 mL sodium chloride 0.9% prefilled syringe FDA approved for dilution and reconstitution (NDC 64253-202-30).
- 2) Evaluate ordering of premixed and vial-to-bag formulations for high usage medications.
- 3) Limit preparation of intravenous push medications on the floor to reduce wastage and conserve inventory.
- 4) As operationally feasible, batch medications requiring sodium chloride 0.9% for injection to reduce wastage and conserve inventory.
- 5) Utilize large volume sodium chloride 0.9% for injection bags for reconstitution and dilution in the pharmacy with the appropriate beyond use dating (6 hours under ISO Class 5 or cleaner, per USP 797 requirements).
  - Do not use sodium chloride 0.9% for irrigation or inhalation as an alternative as these dosage forms are not FDA approved for this use and have not undergone a particulate-matter test.
- 6) Reserve vials for areas where bags would not be ideal or feasible (eg, pre-packaged kits, crash carts).
- 7) Reserve 10 mL prefilled saline syringes for flush and maintenance of central lines.
- 8) Coordinate direct orders with manufacturers and/or monitor designated allocation with wholesalers.
- 9) Adjust inventory of automated dispensing cabinets (eg, Pyxis, Omnicell, etc.) to decrease stock within low use areas and shift stock to address needs.
- 10) If inventory becomes critically low, pull available stock to inpatient pharmacy for inventory control.

### Important Medication Safety Consideration

- 11) Not recommended; however, members have reported in dire and emergent situations, using prefilled saline syringes for medication reconstitution at the discretion of pharmacy and health system leadership with full medication safety committee/officer review. Use of prefilled saline syringes for medication reconstitution is not recommended by the manufacturers or ISMP, with the exception of the Medefil product. If evaluating use of prefilled saline syringes for medication reconstitution due to critically low inventory of sodium chloride 0.9% against these recommendations, members **must** consider the following:
- Prefilled saline syringes are classified as medical devices, not medications. Prefilled saline syringes are approved by the FDA for flushing of vascular access devices; however, not approved for dilution, reconstitution, or administration of medications and use as such is considered “off-label”.
  - Educate staff that the change is only temporary, and due to unique circumstances, to prevent a culture of inappropriately using prefilled saline syringes to reconstitute and administer medications once the drug shortage resolves.
  - There are sterility differences associated with the prefilled saline syringe products. Verify the prefilled saline syringe is “sterile field ready” to prevent the introduction of potential pathogens if pulling back the syringe during reconstitution.
  - Not all prefilled saline syringes are demarcated to provide measured amounts or contain the exact volume displayed.
  - Develop a process for labeling syringes to prevent inadvertent administration of an unlabeled medication in error.
  - Medefil supplies the only 10 mL sodium chloride 0.9% prefilled syringe FDA approved for dilution and reconstitution (NDC 64253-202-30).

## Appendix 1. Comparison of fluids for injection<sup>a</sup>

| Product                                           | Active ingredient(s) | Inactive ingredient(s)                                                                                     | Osmolality              | Preservative      | Comment(s)                                                                                                                                                                                                                                                      |
|---------------------------------------------------|----------------------|------------------------------------------------------------------------------------------------------------|-------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sodium chloride 0.9% for injection                | Sodium chloride      | <ul style="list-style-type: none"> <li>Hydrochloric acid</li> <li>Water</li> </ul>                         | Isotonic                | Preservative-free | <ul style="list-style-type: none"> <li>Sterile, nonpyrogenic</li> </ul>                                                                                                                                                                                         |
| Sterile water for injection                       | Water                | -                                                                                                          | Not isotonic, hemolytic | Preservative-free | <ul style="list-style-type: none"> <li>Sterile, nonpyrogenic</li> <li>Do not administer intravenously unless rendered nearly isotonic</li> </ul>                                                                                                                |
| Bacteriostatic sodium chloride 0.9% for injection | Sodium chloride      | <ul style="list-style-type: none"> <li>Benzyl alcohol</li> <li>Hydrochloric acid</li> <li>Water</li> </ul> | Isotonic                | Benzyl alcohol    | <ul style="list-style-type: none"> <li>Sterile, nonpyrogenic</li> <li>Not for use in neonates</li> <li>Not for inhalation use</li> <li>Not for use in epidural or spinal anesthetic procedures</li> <li>Not for fluid or sodium chloride replacement</li> </ul> |

<sup>a</sup>Check the package inserts of individual products for specifics

## References

Sodium chloride 0.9% injection. Package insert. Bethlehem, PA: B. Braun Medical; 2018.

Sterile water injection. Package insert. Glendale Heights, IL: Medefil; 2020.

Bacteriostatic sodium chloride 0.9% injection. Package insert. Lake Forest, IL: Hospira; 2020.

Sodium chloride 0.9% injection. Package insert. Glendale Heights, IL: Medefil; 2020.

United States Pharmacopeia (USP-797). United States Pharmacopeial Convention; 2021. Accessed January 4, 2022.

Infectious Control Resource. Prevention Strategies for IC Practitioners and Professional Nurses. Accessed January 4, 2022. [https://hadawayassociates.com/uploads/3/5/4/4/35447364/misuse\\_of\\_prefilled\\_copy.pdf](https://hadawayassociates.com/uploads/3/5/4/4/35447364/misuse_of_prefilled_copy.pdf).

Institute for Safe Medication Practices (ISMP). ISMP Safe Practice Guidelines for Adult IV Push Medications; 2015. Accessed January 4, 2022. <https://www.ismp.org/sites/default/files/attachments/2017-11/ISMP97-Guidelines-071415-3.%20FINAL.pdf>.

Institute for Safe Medication Practices (ISMP). Is it really saline?. Published November 15, 2018. Accessed January 4, 2022. <https://www.ismp.org/resources/it-really-saline>.

FDA. MAUDE adverse event report: Prefilled saline flush syringe. Updated December 31, 2021. Accessed January 4, 2022. [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi\\_id=2501052](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=2501052).

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