

# Supply chain disruption report

Pfizer Rocky Mount facility

## Situation

On July 19, 2023, the Pfizer Rocky Mount facility in North Carolina was impacted by an EF-3 tornado.

## Background

According to [Pfizer's website](#), the Rocky Mount plant is one of the largest sterile injectable facilities in the world, with more than 1.4 million square feet of facility space on 250 acres in Eastern North Carolina.

[Nearly 25% of Pfizer's sterile injectables, which is approximately 8% of all sterile injectables used in the US hospitals are manufactured at this plant.](#) Pfizer manufactures products across many categories at this plant including anesthesia, analgesia, therapeutics, anti-infectives, and neuromuscular blockers.

A [Pfizer press release](#) and an [FDA statement document](#) were released on July 21. In a customer letter, Pfizer identified a subset of Rocky Mount products ([Appendix 3](#)) that may experience continued or new supply disruptions in the near-term due to this weather event.

While the Rocky Mount facility is closed Pfizer encourages procurement of product normally as the assessment of the facility continues.

USP has released an assessment of the impacted products. Additionally, [EDSA](#) has released a statement to address the impacted facility.

## Assessment

### Market analysis

The included market analysis in [Appendix 1](#) and [Appendix 2](#) outlines the identified subset of Rocky Mount products provided in the Pfizer customer letter that may experience continued or new supply disruptions in the near-term due to this weather event. Per Pfizer, this subset is based on Pfizer market share and inventory levels of less than 3 months across Pfizer distribution centers and the wholesale chain.

Of the 65 NDCs provided by Pfizer in their customer letter, the market analysis is at the molecule level, of which there are 34 unique molecules. The market analysis includes Vizient contract information, identifies essential medications, available Vizient mitigation strategies, and additional manufacturers in the market. Of note, the market shares provided in [Appendix 1](#) and [Appendix 2](#) are based on total Pfizer units regardless of manufacturing site.

## Recommendation

### Mitigation strategies

Mitigation strategies for select products are provided as links in [Appendix 1](#) and [Appendix 2](#). The mitigation strategies are intended to provide a ready to use document for pharmacy leadership and frontline staff with relevant clinical and operational mitigation strategies for addressing drug shortages. The strategies are developed in coordination with the Member Drug Shortage Mitigation Group to provide peer-reviewed validation of the mitigation recommendations.

### Drug shortage stewardship
























Vizient encourages hospitals and health systems to exercise the principles of [drug shortage stewardship](#) when ordering, prescribing, and administering medications affected by supply constraints to preserve availability for vulnerable patient populations.

## Vizient Resources

Refer to the [Market Disruption Brief](#) for the specifics and the most up to date information of current conditions, Vizient's response, call to action for members, distributor actions, and Pfizer contact information. Please review the [Vizient Drug shortages alert webpage](#) for the most current shortage information. The full library of Vizient Drug shortage mitigation strategies can be accessed on the [Vizient Drug shortages resource](#) webpage.

## Appendix 1. Market analysis of Rocky Mount products with Less Than 3 Months' Inventory in the Distribution Chain<sup>a,b</sup>

Drug	Mitigation Strategy Available	Supplier Market Share <sup>c,d</sup>	Contract Suppliers <sup>e</sup>
Acetylcysteine solution, inhalation	No	Pfizer (5%), American Regent, Fresenius Kabi	Pfizer, American Regent, Sagent
Aminocaproic acid injection	No	Pfizer (31%), American Regent	American Regent
Aminophylline injection 	No	Pfizer (100%)	Pfizer
Atropine sulfate injection 	No	Pfizer (16%), Accord Healthcare, American Regent, Intl Med System	Pfizer, Accord, Amphastar, Hikma, Medefil, American Regent
Bacteriostatic sodium chloride injection	No	Pfizer (77%), Fresenius Kabi	Pfizer, Fresenius Kabi
Bupivacaine 0.75% intrathecal injection	Yes	Pfizer (100%) <sup>f</sup>	Pfizer
Butorphanol injection	No	Pfizer (100%)	Pfizer
Calcium chloride injection 	Yes	Pfizer (1.2%), American Regent, Internatl Labs, Medefil Inc	Pfizer, American Regent, Amphastar, Medefil
Dextrose 25% in water injection	Yes	Pfizer (100%)	Pfizer
Dextrose 50% in water injection	Yes	Pfizer (40%), ICU Medical Inc, Intl Med System	Pfizer, Amphastar, ICU Medical
Dobutamine injection 	Yes	Pfizer (60%), Baxter I.V. Sys Div	Pfizer, Baxter
Dopamine injection 	No	Pfizer (40%), Baxter Pharm Div, Hikma Pharmaceut	Pfizer, Baxter
Epinephrine injection 	Yes	Pfizer (6%) <sup>g</sup> , Amneal, BPI Labs, Intl Med System, Kaleo, Par, Teva, Viatris	Pfizer, Amneal, Amphastar, BPI Labs, Par, US World Meds, Viatris
Fentanyl citrate injection 	No	Pfizer (67%), Fresenius Kabi, Hikma	Pfizer, Exela, Fresenius Kabi, Hikma
Heparin in 0.45% sodium chloride injection	No	Pfizer (65%), Fresenius Kabi	Pfizer, Fresenius Kabi
Lidocaine injection 	Yes	Pfizer (18%), Eugia, Fresenius Kabi, Hikma, Internatl Labs, Spectra Med Dev	Pfizer, Fresenius Kabi
Lidocaine with epinephrine injection	Yes	Pfizer (5%), Cook-Waite, Fresenius Kabi, Henry Schein Inc.	Pfizer, Fresenius
Linezolid injection 	No	Pfizer (29%), Eugia US LLC, Fresenius Kabi, Hikma Pharmaceut, Piramal Healthcare, Sandoz, Sun Pharmaceutical	Pfizer, Piramal
Magnesium sulfate injection 	Yes	Pfizer (10%), B. Braun Medical, Fresenius Kabi, Viatris, WG Critical Care	Pfizer, Baxter, Fresenius Kabi
Mannitol injection	No	Pfizer (22%), B. Braun Medical, Baxter I.V. Sys Div, Fresenius Kabi, ICU Medical Inc.	Pfizer, Baxter, ICU Medical
Midazolam injection 	No	Pfizer (31%), Almaject Inc, Athenex Ph, Avet Pharma, Fresenius Kabi USA, Hikma Pharmaceut, WG Critical Care	Pfizer, Exela, Fresenius Kabi, Hikma, WG Critical Care
Morphine sulfate injection	No	Pfizer (47%), Fresenius Kabi, Hikma Pharmaceut	Pfizer, Amphastar, Fresenius Kabi, ICU Medical, Piramal
Nalbuphine injection	No	Pfizer (100%)	Pfizer

Drug	Mitigation Strategy Available	Supplier Market Share <sup>c,d</sup>	Contract Suppliers <sup>e</sup>
Naloxone injection  	No	<b>Pfizer (16%)</b> , Baxter I.V. Sys Div, Dr Reddys Lab, Eugia US LLC, Hikma Pharmaceut, Intl Med System, Somerset Therap, Viatris	<b>Pfizer, Amphastar, Hikma, Viatris</b>
Phytonadione (vitamin K1) injection  	Yes	<b>Pfizer (33%)</b> , Cipla USA, Inc., Dr Reddys Lab, Intl Med System	<b>Pfizer, Amphastar, Cipla</b>
Potassium acetate injection  	<b>Yes</b>	<b>Pfizer (89%)</b> , Exela Pharma Sci	<b>Pfizer, Exela</b>
Potassium chloride injection 	No	<b>Pfizer (38%)</b> , B. Braun Medical, Baxter IV Sys Div, Baxter Pharm Div, Fresenius Kabi	<b>Pfizer, Baxter, ICU Medical, Fresenius Kabi</b>
Potassium phosphate injection  	<b>Yes</b>	<b>Pfizer (62%)</b> , CMP Pharma Inc, Fresenius Kabi	<b>Pfizer, CMP Pharma, Fresenius Kabi</b>
Rocuronium injection  	<b>Yes</b>	<b>Pfizer (20%)</b> , Almaject Inc, Baxter I.V. Sys Div, Eugia US LLC, Fresenius Kabi, Hikma Pharmaceut, Piramal Healthcare, Sandoz, Viatris, X-Gen Pharm Inc	<b>Pfizer</b>
Sodium acetate injection  	<b>Yes</b>	<b>Pfizer (68%)</b> , Woodward Pharma	<b>Pfizer</b>
Sodium bicarbonate 4.2% injection  	No	<b>Pfizer (58%)</b> , Fresenius Kabi, Exela Pharma Sci	<b>Pfizer</b>
Sodium bicarbonate 7.5% injection 	No	<b>Pfizer (100%)</b>	<b>Pfizer</b>
Sodium bicarbonate 8.4% injection  	No	<b>Pfizer (59%)</b> , Exela Pharma Sci, Fresenius Kabi, Intl Med System	<b>Pfizer, Amphastar</b>
Sodium chloride 23.4% injection  	No	<b>Pfizer (32%)</b> , Fresenius Kabi	<b>Pfizer</b>
Sodium phosphate injection 	<b>Yes</b>	<b>Pfizer (54%)</b> , Fresenius Kabi	<b>Fresenius Kabi</b>
Succinylcholine injection  	<b>Yes</b>	<b>Pfizer (62%)</b> , CMP Pharma Inc, Fresenius Kabi	<b>Sandoz</b>

<sup>a</sup>Market shares are based on total Pfizer units regardless of manufacturing site. For example, a Pfizer market share of 100% does not necessarily mean all the production was done at the Rocky Mount facility, that level of detail is not known at this time.

<sup>b</sup>Refer to the [USP report](#) for market shares of the individual NDCs provided in the Pfizer customer letter

<sup>c</sup>IQVIA analysis at level of drug name and dosage form (e.g., inhalation, injection, intrathecal), unless otherwise specified; includes year-to-date 2023 (January 2023 to May 2023); suppliers where market share < 1% excluded and Akorn market share excluded

<sup>d</sup>Does not include 503b market share information.

<sup>e</sup>Refer to the [Vizient Catalog](#) for contracted alternative NDCs

<sup>f</sup>Hospira (Pfizer) manufactures bupivacaine hydrochloride 0.75% intrathecal solution as both Marcaine Spinal and Bupivacaine Spinal. Only Bupivacaine Spinal (NDC 00409-3613-01) is listed as being impacted with less than 3 months' supply. Brookfield Pharmaceuticals LLC has recently brought another product to market (NDC 71351-0022-10), which was not captured in the IQVIA data set.

<sup>g</sup>For 1 mg/10 mL epinephrine syringes, Pfizer has 32.81% market share with Intl Med System being the alternate supplier

 = essential medication,  = Novaplus Enhanced Supply

## Appendix 2. Guidance for products with 100% Pfizer market share<sup>ab</sup>

Product	Mitigation Strategy
<b>Aminophylline injection</b>	<ul style="list-style-type: none"> <li>Utilized primarily for refractory status asthmaticus in pediatric patients. Reserve for patients not responding to other status asthmaticus pharmacotherapy (e.g., albuterol, terbutaline, corticosteroids, magnesium, ipratropium, etc.).</li> <li>To conserve inventory, operationalize drawing up patient specific doses.</li> </ul>
<b>Bupivacaine 0.75% intrathecal injection</b>	<ul style="list-style-type: none"> <li>Hospira (Pfizer) manufactures bupivacaine hydrochloride 0.75% intrathecal solution as both Marcaine Spinal and Bupivacaine Spinal. Only Bupivacaine Spinal (NDC 00409-3613-01) is listed as being impacted with less than 3 months' supply.</li> <li>Brookfield Pharmaceuticals LLC has recently brought another product to market (NDC 71351-0022-10). This product was not captured in the IQVIA data.</li> <li>Refer to the available <a href="#">mitigation strategy</a> for additional information, which includes compounding information.</li> </ul>
<b>Butorphanol injection</b>	<ul style="list-style-type: none"> <li>Utilized primarily for analgesia during labor. Evaluate and discuss alternatives with obstetricians and other institutional specialists, taking into consideration risk of respiratory depression with certain alternatives.</li> <li>Consider using alternative opioids and other analgesic options as clinically appropriate.</li> <li>To avoid pruritis associated with certain opioids consider pre-medication with an appropriate agent.</li> </ul>
<b>Dextrose 25% in water injection</b>	<ul style="list-style-type: none"> <li>Prioritize for treatment of acute symptomatic episodes of hypoglycemia in infants and children.</li> <li>Refer to the available <a href="#">mitigation strategy</a> for additional information.</li> </ul>
<b>Nalbuphine injection</b>	<ul style="list-style-type: none"> <li>Utilized primarily for analgesia during labor. Evaluate and discuss alternatives with obstetricians and other institutional specialists, taking into consideration risk of respiratory depression with certain alternatives.</li> <li>Consider using alternative opioids and other analgesic options as clinically appropriate.</li> <li>To avoid pruritis associated with certain opioids consider pre-medication with an appropriate agent.</li> </ul>
<b>Sodium bicarbonate 7.5% injection</b>	Utilize sodium bicarbonate 4.2% and 8.4% as alternatives, as clinically appropriate.

<sup>a</sup>Market shares are based on total Pfizer units regardless of manufacturing site. For example, a Pfizer market share of 100% does not necessarily mean all the production was done at the Rocky Mount facility, that level of detail is not known at this time.

<sup>b</sup>IQVIA analysis at level of drug name and dosage form (e.g., inhalation, injection, intrathecal), unless otherwise specified; includes year-to-date 2023 (January 2023 to May 2023); suppliers where market share < 1% excluded and Akorn market share excluded

## Appendix 3. Pfizer Hospital Rocky Mount Products with Less Than 3 Months' Inventory in the Distribution Chain

NDC	Product Description
00409-3308-03	Acetylcysteine Solution, USP 6 g/30 mL (200 mg/mL) Multiple Dose Glass Teartop Vial
00409-4346-73	Aminocaproic Acid Injection, USP 5 g/20 mL (250 mg/mL) Single Dose Plastic Fliptop Vial
00409-5921-01	Aminophylline Injection, USP 250 mg/10 mL (25 mg/mL) Single Dose Glass Fliptop Vial
00409-1630-10	Atropine Sulfate Injection, USP (Adult) 1 mg/10 mL (0.1 mg/mL) ANSYR™ Plastic Syringe
00409-4911-34	Atropine Sulfate Injection, USP (Adult) 1 mg/10 mL (0.1 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1 1/2")
00409-1966-12	Bacteriostatic 0.9% Sodium Chloride Injection, USP 10 mL Multiple Dose LifeShield™ Plastic Fliptop Vial
00409-3613-01	Bupivacaine 0.75% Spinal (bupivacaine in dextrose injection, USP) 15 mg/2 mL (7.5 mg/mL) Glass Ampoule
00409-1623-01	Butorphanol Tartrate Injection, USP, CIV 1 mg/mL Single Dose Glass Fliptop Vial
00409-1626-01	Butorphanol Tartrate Injection, USP, CIV 2 mg/mL Single Dose Glass Fliptop Vial
00409-1626-02	Butorphanol Tartrate Injection, USP, CIV 4 mg/2 mL (2 mg/mL) Single Dose Glass Fliptop Vial
00409-1631-10	Calcium Chloride Injection, USP 1 g/10 mL (100 mg/mL) ANSYR™ Plastic Syringe

00409-4928-34	Calcium Chloride Injection, USP 1 g/10 mL (100 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1½")
00409-1775-10	Dextrose Injection 25%, USP (For Infant Use) 2.5 g/10 mL (250 mg/mL) ANSYR™ Plastic Syringe
00409-7517-16	Dextrose Injection 50%, USP 25 g/50 mL (500 mg/mL) ANSYR™ II Plastic Syringe (side/side)
00409-4902-34	Dextrose Injection 50%, USP 25 g/50 mL (500 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (18 G x 1 1/2")
00409-6648-02	Dextrose Injection 50%, USP 25 g/50 mL (500 mg/mL) Single Dose Glass Fliptop Vial
00409-2346-32	Dobutamine in 5% Dextrose Injection, USP 250 mg/250 mL (1 mg/mL) Flexible Container
00409-2347-32	Dobutamine in 5% Dextrose Injection, USP 500 mg/250 mL (2 mg/mL) Flexible Container
00409-3724-32	Dobutamine in 5% Dextrose Injection, USP 1,000 mg/250 mL (4 mg/mL) Flexible Container
00409-7809-22	Dopamine Hydrochloride in 5% Dextrose Injection, USP 400 mg/250 mL (1,600 mcg/mL) Flexible Container
00409-7810-22	Dopamine Hydrochloride in 5% Dextrose Injection, USP 800 mg/250 mL (3,200 mcg/mL) Flexible Container
00409-4933-01	Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) ABBOJECT™ Glass Syringe with Male Luer Lock Adapter and 20-Gauge protected needle
00409-9094-22	Fentanyl Citrate Injection, USP, CII 100 mcg/2 mL (50 mcg/mL) Single Dose Glass Fliptop Vial
00409-9093-35	Fentanyl Citrate Injection, USP, CII 250 mcg/5 mL (50 mcg/mL) Glass Ampoule
00409-7651-62	Heparin Sodium in 0.45% Sodium Chloride Injection, 12,500 USP Units/250 mL (50 USP Units/mL) Flexible Container
00409-7650-62	Heparin Sodium in 0.45% Sodium Chloride Injection, 25,000 USP Units/250 mL (100 USP Units/mL) Flexible Container
00409-3177-01	Lidocaine Hydrochloride and Epinephrine Injection 0.5%, USP (Lidocaine and Epinephrine 1:200,000) 250 mg/50 mL (5 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3178-01	Lidocaine Hydrochloride and Epinephrine Injection 1%, USP (Lidocaine and Epinephrine 1:100,000) 200 mg/20 mL (10 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3178-02	Lidocaine Hydrochloride and Epinephrine Injection 1%, USP (Lidocaine and Epinephrine 1:100,000) 300 mg/30 mL (10 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3178-03	Lidocaine Hydrochloride and Epinephrine Injection 1%, USP (Lidocaine and Epinephrine 1:100,000) 500 mg/50 mL (10 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3181-01	Lidocaine Hydrochloride and Epinephrine Injection 1.5%, USP (Lidocaine and Epinephrine 1:200,000) 450 mg/30 mL (15 mg/mL) Single Dose Glass Fliptop Vial
00409-1209-01	Lidocaine Hydrochloride 1.5% and Epinephrine Injection, USP (Lidocaine and Epinephrine 1:200,000) 75 mg/5 mL (15 mg/mL) Glass Ampoule
00409-3182-03	Lidocaine Hydrochloride and Epinephrine Injection 2%, USP (Lidocaine and Epinephrine 1:100,000) 1,000 mg/50 mL (20 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3182-01	Lidocaine Hydrochloride and Epinephrine Injection 2%, USP (Lidocaine and Epinephrine 1:100,000) 400 mg/20 mL (20 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3182-02	Lidocaine Hydrochloride and Epinephrine Injection 2%, USP (Lidocaine and Epinephrine 1:100,000) 600 mg/30 mL (20 mg/mL) Multiple Dose Glass Fliptop Vial
00409-3183-01	Lidocaine Hydrochloride and Epinephrine Injection 2%, USP (Lidocaine and Epinephrine 1:200,000) 400 mg/20 mL (20 mg/mL) Single Dose Glass Fliptop Vial
00409-9137-05	Lidocaine Hydrochloride Injection 1%, USP (For Cardiac Use Only) 50 mg/5 mL (10 mg/mL) ANSYR™ Plastic Syringe
00409-1323-05	Lidocaine Hydrochloride Injection 2%, USP (For Cardiac Use Only) 100 mg/5 mL (20 mg/mL) ANSYR™ Plastic Syringe
00409-4903-34	Lidocaine Hydrochloride Injection 2%, USP (For Cardiac Use Only) 100 mg/5 mL (20 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1 1/2")
00409-4277-02	Lidocaine Hydrochloride Injection 2%, USP 1,000 mg/50 mL (20 mg/mL) Multiple Dose Plastic Fliptop Vial
00409-4883-01	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) VisIV™ Flexible Container
00409-6729-03	Magnesium Sulfate in Water for Injection 20 g/500 mL (40 mg/mL) Flexible Container
00409-4031-01	Mannitol Injection, USP 12.5 g/50 mL Single Dose Glass Fliptop Vial (25% concentration)

00409-2305-17	Midazolam Injection, USP CIV 2 mg/2mL (1 mg/mL) Single Dose Glass Fliptop Vial
00409-2308-02	Midazolam Injection, USP CIV 10 mg/2 mL (5 mg/mL) Single Dose Glass Fliptop Vial
00409-1134-03	Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant) 1,000 mg/20 mL (50 mg/mL) Single Dose Glass Fliptop Vial
00409-1134-05	Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant) 2,500 mg/50 mL (50 mg/mL) Single Dose Glass Fliptop Vial
00409-1465-01	Nalbuphine Hydrochloride Injection 20 mg/mL Glass Ampoule
00409-1215-01	Naloxone Hydrochloride Injection, USP 0.4 mg/mL Single Dose Glass Fliptop Vial
00409-8183-01	Potassium Acetate Injection, USP 40 mEq/20 mL (2 mEq/mL) Single Dose Plastic Fliptop Vial
00409-6651-06	Potassium Chloride for Injection Concentrate, USP 20 mEq/10 mL (2 mEq/mL) Single Dose Plastic Fliptop Vial
00409-7295-01	Potassium Phosphates Injection, USP, 45 mM P/15 mL (3 mM P/mL) Single Dose Glass Fliptop Vial
00409-6629-02	Quelicin™ (succinylcholine chloride injection, USP) 200 mg/10 mL (20 mg/mL) Multiple Dose Glass Fliptop Vial
00409-9558-05	Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) Multiple Dose Glass Fliptop Vial
00409-7299-73	Sodium Acetate Injection, USP 40 mEq/20 mL (2 mEq/mL) Single Dose Plastic Fliptop Vial
00409-3299-06	Sodium Acetate Injection, USP 200 mEq/100 mL (2 mEq/mL) Pharmacy Bulk Package Glass Fliptop Vial
00409-5534-14	4.2% Sodium Bicarbonate Injection, USP 5 mEq/10 mL (0.5 mEq/mL) ABBOJECT® Glass Syringe with Male Luer Lock Adapter and 20-Gauge protected needle
00409-5555-02	4.2% Sodium Bicarbonate Injection, USP 5 mL Fliptop Vial
00409-4916-14	7.5% Sodium Bicarbonate Injection, USP 44.6 mEq/50 mL (0.9 mEq/mL) LifeShield™ ABBOJECT™ Glass Syringe with Male Luer Lock Adapter and 18-Gauge protected needle
00409-6637-14	8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) LifeShield® ABBOJECT® Glass Syringe Male Luer Lock Adapter and 18-Gauge protected needle
00409-1141-02	23.4% Sodium Chloride Injection, USP 400 mEq/100 mL (4 mEq/mL) Pharmacy Bulk Package Glass Fliptop Vial
00409-7391-72	Sodium Phosphates Injection, USP 45 mMol/15 mL (3 mMol P/mL) Single Dose Plastic Fliptop Vial
00409-5816-11	Sterile Empty Vial 10 mL Glass Bottle
00409-5816-31	Sterile Empty Vial 30 mL Glass Bottle
00409-9158-01	Vitamin K1 (phytonadione injectable emulsion, USP) 10 mg/mL Glass Ampoule

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