



Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

April 6, 2018

Update to Pfizer Injectables Carpuject™ and iSecure™ Prefilled Syringe Portfolio Supply Interruption and Actions

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply so that our customers can develop contingency plans to facilitate patient care. I am writing to provide you with updated information on the supply status of our Carpuject™ and iSecure™ products, and the steps we are taking to expedite getting additional product to market. Our teams are committed to restoring supply, and are exploring multiple avenues in which to do this.

Following a quality investigation related to an issue with an incoming component supplied by a third-party supplier, Pfizer paused production of Carpuject product. As part of that investigation, we have successfully identified and addressed the root cause, and have restarted production of our Carpuject prefilled syringes. The first shipments of product manufactured after the restart are expected to reach wholesalers in July 2018. We will work to expedite the process where possible.

Secondly, we previously communicated that we had finished product lots of iSecure and Carpuject configurations that had been placed on hold due to the same third-party supplier issue. We continue to evaluate the product on hold to determine if and when it can be released. We will keep you posted as we complete the product assessments.

We continue to work towards full recovery dates for prioritized prefilled syringes of 1Q19 and deprioritized syringes of 2Q19. Pfizer understands the importance of this situation and its impact on patient care. We are committed to increasing supply of product, and will do everything we can to achieve that goal. You may reach out to the Pfizer Injectables leadership team at PfizerInjectables@Pfizer.com with any questions or contact your Pfizer Injectables representative; we will respond as quickly as possible.

Sincerely,

Jodi Perez

Senior Director
Portfolio Team Lead, Drug Delivery Systems

TABLE – List of Carpuject and iSecure Products

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diazepam Injection, USP, CIV	00409-1273-32	10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1316-32	5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-05	0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1283-31	1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1312-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Labetalol Hydrochloride Injection, USP	00409-2339-34	20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1985-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-01	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1891-01	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Naloxone Hydrochloride Injection, USP	00409-1782-69	0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)