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

March 1, 2021

Product Label and NDC Change for
Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL)
ABBOJECT® Syringe

Dear Valued Customer,

Pfizer Hospital is committed to keeping you informed of any product changes so appropriate plans can be made to facilitate patient care. Pfizer has received approval from the US Food and Drug Administration (FDA) for **Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) ABBOJECT® Syringe**, which was previously marketed as a grandfathered product. This recent approval process has resulted in a product label and NDC change. In addition, a component of the device has changed color. It is important to know that while there is a change to the indication, the concentration remains the same.

Pfizer understands the importance of this label change and wanted to bring this information to your attention ahead of the transition. To support this transition, we have included a side-by-side view of the current and new label information along with additional product detail listed in the table below.

IMPORTANT – Please keep in mind that as we transition to the new NDC, both labels will be in the marketplace temporarily until the expiry of the current NDC on or before May 1, 2022. The new NDC will be available for direct orders beginning the week of March 15, 2021, and available via wholesalers and distributors beginning the week of March 22, 2021 (locational inventory may vary).

CATEGORY	CURRENT	NEW
Unit of Sale NDC	00409-4921-34	00409-4933-01
Unit of Sale Barcode	(01)10304094921348	(01)00304094933016
Unit of Use NDC	00409-4921-20	00409-4933-11
Unit of Use Barcode	(01)00304094921204	(01)10304094933112
Unit of Sale Pack Size	1 Box of 10	No Change
Unit of Use Pack Size	1 Syringe	No Change
Description	Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) ABBOJECT™ Glass Syringe	Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) ABBOJECT™ Glass Syringe

Formulation	*Each milliliter (mL) contains epinephrine 0.1 mg; sodium chloride 8.16 mg; sodium metabisulfite added 0.46 mg; citric acid, anhydrous 2 mg and sodium citrate, dihydrate 0.6 mg added as buffers. May contain additional citric acid and/or sodium citrate for pH adjustment. pH 3.3 (2.2 to 5.0).*	*Each milliliter contains 0.1 mg epinephrine, 8.16 mg sodium chloride, 0.46 mg sodium metabisulfite, and 2.13 mg citric acid, anhydrous and 0.41 mg sodium citrate, dihydrate added as buffers. Additional citric acid and/or sodium citrate may be added for pH adjustment. pH range of 2.3-3.5.*
Indication	***INDICATIONS AND USAGE*** *Epinephrine Injection, USP is indicated for intravenous injection in (1) treatment of acute hypersensitivity (anaphylactoid reactions to drugs, animal serums and other allergens),(2) treatment of acute asthmatic attacks to relieve bronchospasm not controlled by inhalation or subcutaneous administration of other solutions of the drug and (3) treatment and prophylaxis of cardiac arrest and attacks of transitory atrioventricular (A-V) heart block with syncopal seizures (Stokes-Adams Syndrome).* *In acute attacks of ventricular standstill, physical measures should be applied first. When external cardiac compression and attempts to restore the circulation by electrical defibrillation or use of a pacemaker.*	***INDICATIONS AND USAGE*** *Epinephrine is a non-selective alpha- and beta-adrenergic agonist indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.*
Dosage and Administration	***DOSAGE AND ADMINISTRATION*** *Epinephrine Injection, USP is administered by intravenous injection and/or in cardiac arrest, by intracardiac injection into the left ventricular chamber or via endotracheal tube directly into the bronchial tree. The adult intravenous dose for hypersensitivity reactions or to relieve bronchospasm usually ranges from 0.1 to 0.25 mg (1 to 2.5 mL of 0.1 mg/mL solution), injected slowly. Neonates may be given a dose of 0.01 mg per kg of body weight; for the infant 0.05 mg is an adequate initial dose and this may be repeated at 20 to 30-minute intervals in the management of asthma attacks.* *In cardiac arrest, 0.5 to 1.0 mg (5 to 10 mL of 0.1 mg/mL solution) may be given. During a resuscitation effort, 0.5 mg (5 mL) should be administered intravenously every five minutes.* *Intracardiac injection should only be administered by personnel well trained in the technique, if there has not been sufficient time to establish an intravenous route. The intracardiac dose usually ranges from 0.3 to 0.5 mg (3 to 5 mL of 0.1 mg/mL solution).* *Alternatively, if the patient has been intubated, epinephrine can be injected via the endotracheal tube directly into the bronchial tree at the same dosage as for intravenous injection. It is rapidly absorbed through the lung capillary bed.*	***DOSAGE AND ADMINISTRATION*** *Hypotension associated with septic shock:* • *Dilute 10 mL (1 mg) of epinephrine from the syringe in 1,000 mL of 5 percent dextrose solution or 5 percent dextrose and sodium chloride solution to produce a 1 mcg per mL dilution. The diluted solutions can be stored for up to 4 hours at room temperature or 24 hours under refrigerated conditions.* • *To provide hemodynamic support in septic shock associated hypotension in adult patients, the suggested dosing infusion rate of intravenously administered epinephrine is 0.05 mcg/kg/min to 2 mcg/kg/min, and is titrated to achieve a desired mean arterial pressure (MAP). The dosage may be adjusted periodically, such as every 10 - 15 minutes, in increments of 0.05 mcg/kg/min to 0.2 mcg/kg/min, to achieve the desired blood pressure goal.* • *After hemodynamic stabilization, wean incrementally over time, such as by decreasing doses of epinephrine every 30 minutes over a 12- to 24-hour period.*

Prescribing Information	*For more information, please review the **current** Prescribing Information*	***New** Prescribing Information is pending and will be posted on Pfizer.com once product is available.*
Shelf Life	21 months	15 months
Stopper Color	Blue	Gray

For your convenience, we have included the wholesaler numbers for the new NDC.

WHOLESALER NUMBER TABLE

NEW NDC Wholesaler Numbers					
NEW Unit of Sale NDC	**NEW** Unit of Use NDC	ABC	Cardinal	McKesson	Morris & Dickson
00409-4933-01	00409-4933-11	10253462	5698691	1594399	963504

For medical inquiries, please do not hesitate to contact Pfizer Medical Information at 1-800-438-1985. For any other questions, please reach out to your sales representative or your account executive.

Thank you,

Brian Pederson
Portfolio Director, Opioids and Pre-Filled Syringes
Pfizer Hospital Business Unit U.S.

Important Safety Information Epinephrine Injection, USP ABBOJECT® Glass Syringe

Indications and Usage
Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

Important Safety Information
Monitor blood pressure frequently and titrate to avoid excessive increases in blood pressure. Patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types may experience severe, prolonged hypertension when given epinephrine. There is potential for pulmonary edema which may be fatal.

Epinephrine may induce serious cardiac arrhythmias and myocardial ischemia, particularly in patients with underlying heart disease.

Avoid extravasation into tissues to prevent local necrosis.

Epinephrine constricts renal blood vessels, which may result in oliguria or renal impairment. Presence of sulfite in this product should not deter use for hypotension associated with septic shock. In susceptible patients consider using a formulation of epinephrine or another vasoconstrictor that does not contain sodium metabisulfite.

Most common adverse reactions to systemically administered epinephrine are headache, anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, diaphoresis, nausea/vomiting, and or respiratory difficulties. Arrhythmias, including fatal ventricular fibrillation, rapid rises in blood pressure producing cerebral hemorrhage, and angina have occurred.

Drugs that counter the pressor effects of epinephrine include alpha-blockers, vasodilators, diuretics, antihypertensives, ergot alkaloids, and phenothiazine antipsychotics.

Drugs potentiating the pressor effects of epinephrine include sympathomimetics, beta-blockers, tricyclic antidepressants, MAO inhibitors, catechol-O-methyltransferase (COMT) inhibitors, clonidine, doxapram, oxytocin, levothyroxine sodium and certain antihistamines.

Drugs that increase the arrhythmogenic potential of epinephrine include beta blockers, cyclopropane and halogenated hydrocarbon anesthetics, quinidine, antihistamines, exogenous thyroid hormones, diuretics, and cardiac glycosides.

Potassium-depleting drugs including corticosteroids, diuretics, and theophylline potentiate the hypokalemic effects of epinephrine.