

PFIZER-BIONTECH COVID-19 VACCINE- bnt162b2 injection, suspension
Pfizer Manufacturing Belgium NV

Pfizer-BioNTech Covid-19 Vaccine

PRINCIPAL DISPLAY PANEL - 0.2 mL Vial Label - 0078-1

Pfizer-BioNTech COVID-19 Vaccine
DILUTE PRIOR TO USE
Age 2y to < 5y
After dilution - 10 doses of 0.2 mL
For intramuscular use. Contains no preservative.
For use under Emergency Use Authorization.
After dilution store at 2 to 25°C (35 to 77°F) and
discard after 6 hours.
Dilution date and time:

NDC 59267-0078-1



PRINCIPAL DISPLAY PANEL - 0.2 mL Vial Carton Label - 0078-2

NDC 59267-0078-2
Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection
DILUTE PRIOR TO USE
195 Multiple Dose Vials
After dilution each vial contains
10 doses of 0.2 mL
For age 2 years to < 5 years

BIONTECH

Pfizer

For storage and expiry information, see
FDA-authorized Fact Sheet or scan QR code.
Store in this carton to protect from light.
MUST BE DILUTED BEFORE USE with sterile
0.9% Sodium Chloride Injection, USP (not supplied).
After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).
Discard 6 hours after dilution. Contains no preservative.
For use under Emergency Use Authorization.

Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Manufactured by
Pfizer Inc.
New York, NY 10017

Rx only

GTIN: 00359267007827

LOT/MFG:

PAA177570

NDC 59267-0078-2

Pfizer-BioNTech COVID-19 Vaccine

Suspension for Intramuscular Injection

DILUTE PRIOR TO USE

195 Multiple Dose Vials

After dilution each vial contains

10 doses of 0.2 mL

For age **2** years to **< 5** years



For storage and expiry information, see
FDA-authorized Fact Sheet or scan QR code.

Store in this carton to protect from light.

MUST BE DILUTED BEFORE USE with sterile
0.9% Sodium Chloride Injection, USP (not supplied).

After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).

Discard 6 hours after dilution. Contains no preservative.

For use under Emergency Use Authorization.

Rx only



Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Manufactured by
Pfizer Inc.
New York, NY 10017

PAA177570

GTIN: 00359267007827
LOT/MFG:

**OVERPRINT
AREA**

**INLINE
DM
AREA**

Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection

DILUTE PRIOR TO USE

195 Multiple Dose Vials

After dilution each vial contains

10 doses of 0.2 mL

For age **2** years to **< 5** years

For storage and expiry information, see
FDA-authorized Fact Sheet or scan QR code.
Store in this carton to protect from light.

**MUST BE DILUTED
BEFORE USE** with
sterile 0.9% Sodium
Chloride Injection,
USP (not supplied).
After dilution, store
the vaccine at 2°C to
25°C (35°F to 77°F).
Discard 6 hours
after dilution.
Contains no
preservative.

PAA177570

GTIN: 00359267007827
LOT/MFG:

**OVERPRINT
AREA**

**INLINE
DM
AREA**

PRINCIPAL DISPLAY PANEL - 0.2 mL Vial Carton - 0078-4

Pfizer-BioNTech
COVID-19 Vaccine
Suspension for Intramuscular Injection

DILUTE PRIOR TO USE
 10 Multiple Dose Vials
 After dilution each vial contains
 10 doses of 0.2 mL
 For age 2 years to < 5 years

BIONTECH
 Pfizer

NDC 59267-0078-4

Rx only



PFIZER-BIONTECH COVID-19 VACCINE

bnt162b2 injection, suspension

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:59267-0078
---------------------	---------	---------------------------	----------------

Route of Administration INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOZINAMERAN (UNII: 5085ZFP6SJ) (TOZINAMERAN - UNII:5085ZFP6SJ)	TOZINAMERAN	3 ug in 0.2 mL

Inactive Ingredients

Ingredient Name	Strength
ALC-0159 (UNII: PJH39UMU6H)	
ALC-0315 (UNII: AVX8DX713V)	
TROMETHAMINE (UNII: 023C2WHX2V)	
TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)	
SUCROSE (UNII: C151H8M554)	
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 043IPI2MOK)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59267-0078-2	195 in 1 CARTON		
1	NDC:59267-0078-1	2 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:59267-0078-4	10 in 1 CARTON		
2	NDC:59267-0078-1	2 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EMERGENCY USE AUTHORIZATION		08/13/2021	

Labeler - Pfizer Manufacturing Belgium NV (370156507)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(59267-0078) , MANUFACTURE(59267-0078) , PACK(59267-0078) , LABEL(59267-0078)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(59267-0078) , MANUFACTURE(59267-0078) , PACK(59267-0078) , LABEL(59267-0078)

Establishment			
Name	Address	ID/FEI	Business Operations
Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC		174350868	ANALYSIS(59267-0078) , API MANUFACTURE(59267-0078)

Establishment			
Name	Address	ID/FEI	Business Operations
Pfizer Inc		004954111	ANALYSIS(59267-0078)

Revised: 11/2021

Pfizer Manufacturing Belgium NV