

**MODERNA COVID-19 VACCINE, BIVALENT- moderna covid-19 vaccine,  
bivalent injection, suspension  
Moderna US, Inc.**

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## **DESCRIPTION**

## **CLINICAL PHARMACOLOGY**

## **INDICATIONS AND USAGE**

## **CONTRAINDICATIONS**

## **WARNINGS**

## **PRECAUTIONS**

### **General**

### **Information for Patients**

### **Laboratory Tests**

### **Interactions**

Drug Interactions

Drug/Laboratory Test Interactions

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

### **Pregnancy**

### **Labor and Delivery**

### **Nursing Mothers**

### **Pediatric Use**

### **Geriatric Use**

## **ADVERSE REACTIONS**

## DRUG ABUSE AND DEPENDENCE

### Controlled Substance

### Abuse

### Dependence

## OVERDOSAGE

## DOSAGE AND ADMINISTRATION

## HOW SUPPLIED

### Package/Label Display Panel

 STORE FROZEN between  $-50^{\circ}$  to  $-15^{\circ}\text{C}$  ( $-58^{\circ}$  to  $5^{\circ}\text{F}$ ). Protect from light. No preservative. After first use, hold at  $2^{\circ}$  to  $25^{\circ}\text{C}$  ( $36^{\circ}$  to  $77^{\circ}\text{F}$ ). Discard after 12 hours. Record date/time of first use: \_\_\_\_\_

703842

 Scan here for FDA-authorized Fact Sheet for dosage and administration, and product expiration dates, or visit [www.modernatx.com/covid19vaccine-eua/](http://www.modernatx.com/covid19vaccine-eua/)

Mfd. for: Moderna US, Inc., Cambridge, MA 02139

**Moderna COVID-19 Vaccine, Bivalent Original and Omicron**  
Suspension for Intramuscular Injection  
For use under Emergency Use Authorization

**BOOSTER DOSES ONLY**

 Vial contains 5 doses of 0.5 mL

NDC 80777-280-05

LOT

NDC 80777-280-05

Moderna COVID-19 Vaccine, Bivalent

Original and Omicron

Suspension for Intramuscular Injection

For use under Emergency Use Authorization

BOOSTER DOSES ONLY

Vial contains 5 doses of 0.5 mL

### Package/Label Display Panel



NDC 80777-280-99

Moderna COVID-19 Vaccine, Bivalent

Original and Omicron

Suspension for Intramuscular Injection

For use under Emergency Use Authorization

BOOSTER DOSES ONLY

STORE FROZEN between -50° to -15°C (-58° to 5°F).

Protect from light

Ten multi-dose vials

Each vial contains 5 doses of 0.5 mL

## MODERNA COVID-19 VACCINE, BIVALENT

moderna covid-19 vaccine, bivalent injection, suspension

### Product Information

<b>Product Type</b>	VACCINE	<b>Item Code (Source)</b>	NDC:80777-280
<b>Route of Administration</b>	INTRAMUSCULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IMELASOMERAN</b> (UNII: 5295LF55B6) (IMELASOMERAN - UNII:5295LF55B6)	IMELASOMERAN	0.1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SM-102</b> (UNII: T7OBQ65G2I)	
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE</b> (UNII: 043IPI2M0K)	
<b>1,2-DIMYRISTOYL-RAC-GLYCERO-3-METHOXYPOLYETHYLENE GLYCOL 2000</b> (UNII: 9X2596CIE0)	
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	
<b>TROMETHAMINE HYDROCHLORIDE</b> (UNII: 383V75M34E)	
<b>ACETIC ACID</b> (UNII: Q40Q9N063P)	
<b>SODIUM ACETATE</b> (UNII: 4550K05C9B)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80777-280-99	10 in 1 CARTON		
1	NDC:80777-280-05	2.5 mL in 1 VIAL; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/13/2022	

**Labeler** - Moderna US, Inc. (117626450)

## Establishment

Name	Address	ID/FEI	Business Operations
ModernaTX, Inc.		116912313	ANALYSIS(80777-280) , API MANUFACTURE(80777-280)

## Establishment

Name	Address	ID/FEI	Business Operations
Catalent Indiana, LLC		172209277	MANUFACTURE(80777-280) , ANALYSIS(80777-280) , LABEL(80777-280) , PACK(80777-280)

## Establishment

Name	Address	ID/FEI	Business Operations
Patheon Manufacturing Services, LLC		079415560	MANUFACTURE(80777-280) , ANALYSIS(80777-280) , LABEL(80777-280) , PACK(80777-280)

Revised: 6/2022

Moderna US, Inc.