

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

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

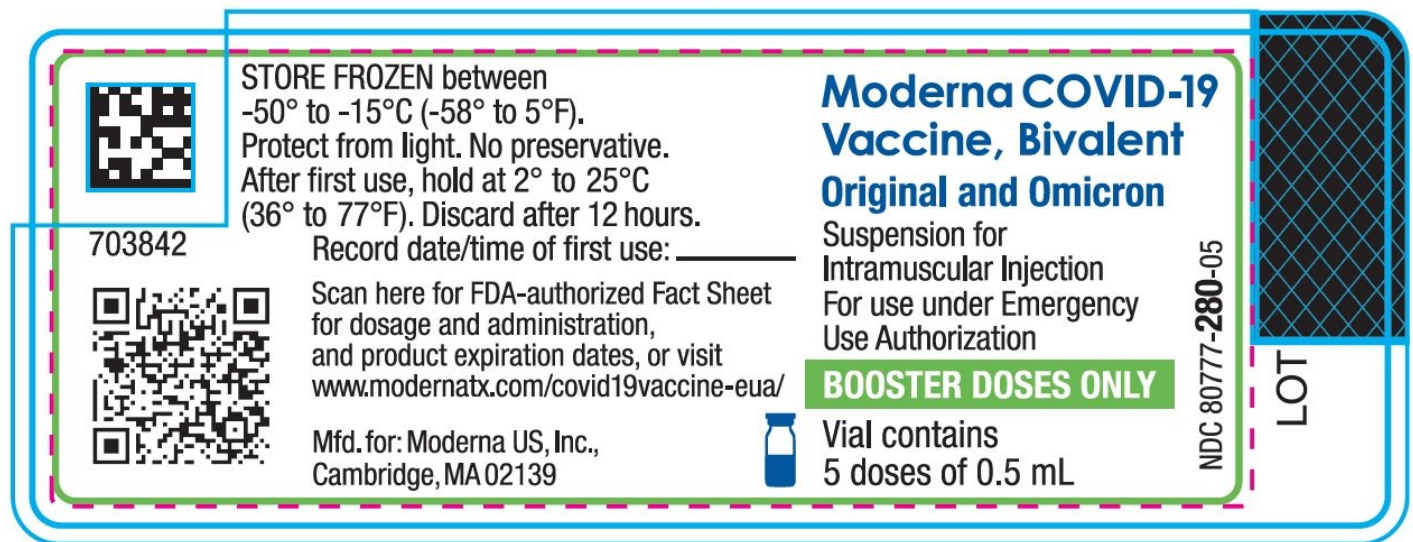
Dependence

OVERDOSAGE

DOSAGE AND ADMINISTRATION

HOW SUPPLIED

Package/Label Display Panel



NDC 80777-280-05

Moderna COVID-19 Vaccine, Bivalent

Original and Omicron

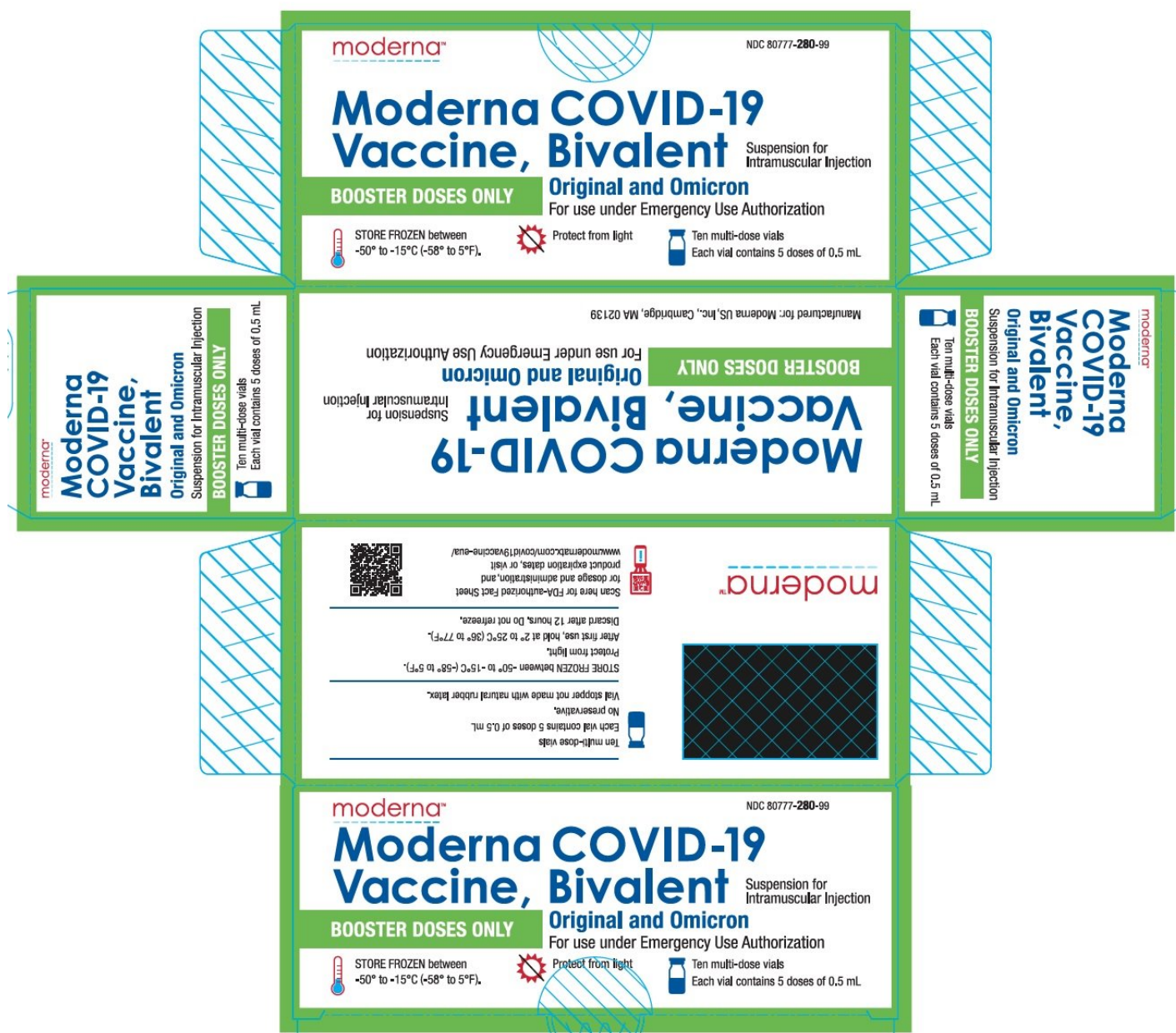
Suspension for Intramuscular Injection

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

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Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SM-102 (UNII: T7OBQ65G2I)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 043IP12M0K)	
1,2-DIMYRISTOYL-RAC-GLYCERO-3-METHOXYPOLYETHYLENE GLYCOL 2000 (UNII: 9X2596CIE0)	
TROMETHAMINE (UNII: 023C2WHX2V)	
TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)	
ACETIC ACID (UNII: Q40Q9N063P)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
SUCROSE (UNII: C151H8M554)	
WATER (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.