

2.2 INTRODUCTION

1. Drug Name

Trade Name: COMIRNATY

Product Name: COVID-19 Vaccine, mRNA

Company code: BNT162b2

Dosage form:

COMIRNATY is formulated as a suspension for injection. Each vial contains 6 doses of 30 micrograms of COVID-19 mRNA Vaccine, embedded in lipid nanoparticles (total volume: 0.45 mL).

2. Pharmacological Class

COMIRNATY is a highly purified single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

3. Mode of Action

Upon intramuscular administration, the RNA is translated to the S protein, which in turn induces a protective immune response in the vaccinated organism.

4. Proposed Clinical Use

Therapeutic indication:

The proposed indication for COMIRNATY is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals ≥ 12 years of age.

COMIRNATY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.

Document Approval Record

Document Name:	COVID-19 Vaccine 2.2 Introduction for adolescent 12-15-year-old 6 month update sBLA (December 2021)
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Signed By:	Date(GMT)	Signing Capacity
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