

## **2.2 INTRODUCTION**

### **1. Drug Name**

Company code: BNT162b2

Dosage form: BNT162b2 is formulated as concentrate for dispersion 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**

BNT162b2 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**

The proposed indication is active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

BNT162b2 is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each). It is recommended to administer the second dose 3 weeks after the first dose.

## Document Approval Record

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