Package Insert
SARS-CoV-2 mRNA Vaccine

Please read the package insert carefully and follow the physician's guidance to use.

1 PRODUCT NAME

Brand name: AWcorna

Generic name: SARS-CoV-2 mRNA Vaccine

2 PRODUCT DESCRIPTION

AWcorna is mRNA-based vaccine encoding the receptor-binding domain (RBD) of spike glycoprotein (S protein) of SARS-CoV-2. The mRNA is produced using *in-vitro* transcription method according to the DNA template and then encapsulated in lipid nanoparticles. This vaccine is a colorless to slightly opalescent, sterile, preservative-free liquid for intramuscular injection in a pre-filled syringe.

Active substances: mRNA encoding the RBD of the S protein of SARS-CoV-2.

Excipients: cationic lipid 9001, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (DMG-PEG2000), potassium dihydrogen phosphate (KH_2PO_4), disodium hydrogen phosphate dodecahydrate ($Na_2HPO_4 \cdot 12H_2O$), sodium chloride (NaCl), sterile water for injection.

3 INDICATION

This product is intended to be used in adults above 18 years of age.

The product is intended for the prevention of COVID-19 caused by the infection of SARS-CoV-2. After vaccine administration, humoral and cellular immunity against SARS-CoV-2 will be induced and the immunity against infection will be obtained. The contents of this vaccine will not lead to SARS-CoV-2 infection or COVID-19.

4 NAME AND STRENGTH OF ACTIVE SUBSTANCE

The vaccine is supplied in single-dose pre-filled syringe with 0.5 mL liquid for injection. Each dose (0.5 mL) of the vaccine contains:

15 μg of mRNA encoding the receptor-binding domain (RBD) of the spike glycoprotein (S protein) of SARS-CoV-2.

5 ADMINISTRATION ROUTE AND VACCINATION SCHEDULE

Administration route:

AWcorna shall be injected intramuscularly into the deltoid muscle of the upper arm. The vaccine should not be injected in and/or near the areas where nerve trunks and/or blood vessels may be located.

Primary series:

A 2-dose primary series (each of 0.5 mL) with an interval of 28 days between doses administered intramuscularly into the deltoid muscle of the upper arm in individuals aged 18 years and above.

Heterologous booster dose:

A heterologous booster dose (0.5 mL) administered intramuscularly into the deltoid muscle of the upper arm in individuals aged 18 years and above who have completed the 2-

dose primary series with inactivated COVID-19 vaccines at least 6 months ago.

6 ADVERSE REACTIONS

The incidence rates of adverse reactions reported in clinical trials, according to the guidance on classifications of adverse events recommended by the Council for International Organizations of Medical Sciences (CIOMS), are classified as: very common (≥ 10%), common (≥ 1% to < 10%), uncommon (≥ 0.1% to < 1%), rare (≥ 0.01% to < 0.1%) and very rare (< 0.01%). The descriptions of adverse reactions for SASR-CoV-2 mRNA vaccine (AWcorna) are summarized as follows:

Clinical Experience with AWcorna

A total of 800 subjects aged 18 years and above were administered with at least one dose of AWcorna in three clinical trials conducted in China. The immediate reactions were observed and recorded for all subjects within 60 minutes after immunization; adverse reactions/events were collected by the investigator through 28 days after immunization; and serious adverse events were collected by the investigator during the entire study period. The following adverse reactions were observed:

Table 1 The Adverse Reactions Reported in Clinical Trials and Classified by CIOMS

	Systemic Adverse Reactions	**Injection-site Adverse Reactions**
Very Common (≥ 10%)	Fever (>37.3℃) Headache Fatigue/asthenia Myalgia Arthralgia Nausea Chill	Pain Pruritus Erythema
Common (≥ 1% to < 10%)	Diarrhea Vomiting Rash	Swelling Induration
Uncommon (≥ 0.1% to < 1%)	Allergic reaction	

The severity of above-mentioned adverse reactions was mainly mild to moderate.

7 CONTRAINDICATIONS

Hypersensitivity to any component of the product, including active substances or any of the excipients listed in section 2.

8 PRECAUTIONS

1) Do not administer this product intravenously. Do not inject in the gluteal area. Avoid injecting into blood vessels.
2) The vaccine should be protected from shaking as much as possible, and shaking well before administration is not necessary. Ensure the vaccine should not be administered if any of the following conditions exists:
   A) The package is damaged or the pre-filled syringe is cracked;
   B) The needle shielding is loosen;
   C) The label is detached;
   D) There are particulate matters and/or discoloration.
3) Use immediately after unsealing. One pre-filled syringe shall be administrated to one

recipient each time according to prescribing information.

4) The vaccination should be postponed in case of fever, or acute diseases, and acute attack of chronic diseases.

5) Appropriate medical treatment and supervision must be available to manage possible severe anaphylactic reactions (e.g., anaphylaxis) following administration of the vaccine. If allergic reactions occur after vaccination, please go to the vaccination site or hospital in time.

6) Cautions should be given for vaccination in individuals with thrombocytopenia, any coagulopathy or those who are receiving anticoagulant treatment.

7) Certain comorbidities have been identified as increasing the risk of severe COVID-19 disease and death. Current data are insufficient to assess vaccine efficacy or vaccine-associated risks in severely immunocompromised individuals. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons and risk-benefit assessment shall be individually performed.

8) Vaccination with AWcorna does not guarantee that all recipients will be prevented from the SARS-CoV-2 infection.

9) Individuals with severe allergic reaction post the First Dose of AWcorna should not be vaccinated with the Second Dose.

9 PREGNANCY AND LACTATION

9.1 Pregnancy

No data are currently available for pregnant women using AWcorna.

9.2 Lactation

Excretion of AWcorna in human milk remains unknown.

10 INTERACTIONS WITH OTHER MEDICAMENTS

No clinical data of AWcorna co-administration with other vaccines are available.

11 OVERDOSE AND TREATMENT

No data are available for overdosage with AWcorna.

12 PHARMACODYNAMIC/PHARMACOKINETICS

Not applicable.

13 STORAGE AND TRANSPORT CONDITIONS

Store and transport between 2ºC to 8ºC, protect from light.

DO NOT SHAKE. DO NOT FREEZE.

Discard if the vaccine has been frozen.

Keep out of children's reach.

14 PACKAGING AVAILABLE

Pre-filled syringe, 1×0.5 mL single human dose, 1 dose per package.

15 INCOMPATIBILITIES

AWcorna shall not be mixed with other medicinal products considering that no

compatibility studies have been conducted.

16 SHELF LIFE

The shelf life of the vaccine is 6 months. Please use before the expiration date printed on the label or small box.

17 NAME AND ADDRESS OF MANUFACTURER/MARKETING AUTHORIZATION HOLDER

Name: Yuxi Walvax Biotechnology Co., Ltd.

Address: No. 83, South Dongfeng Road, High & New Technology Industries Development Zone, Yuxi, Yunnan Province, China

Zip code: 653100

Tel: (+86) 0877-2076210

Fax: (+86) 0877-2076918

Website: www.walvax.com