Abdala ST 50 µg

Suspension for intramuscular injection
Protein subunit COVID-19 vaccine

THIOMERSAL FREE

COMPOSITION

Each dose of 0.5 mL contains:

Receptor Binding Domain (RBD) of SARS-CoV-2 recombinant protein	50 µg
Aluminium hydroxide gel	
Disodium hydrogen phosphate	
Dihydrated dihydrogen sodium phosphate	
Sodium chloride	
Water for injection	

THERAPEUTIC INDICATION

Abdala ST is indicated for the specific active immunization of adults against SARS-CoV-2 infection.

CONTRAINDICATIONS

Persons under 19 years of age.

PRECAUTIONS

As with all vaccines, it is important to have epinephrine hydrochloride solution (1:1000) available so that it can be immediately used in the case of anaphylaxis or an acute hypersensitivity reaction to vaccination. It is therefore recommended that the individual should remain under medical observation for 60 minutes after the administration of the vaccine. A second dose of the vaccine must not be administered to persons that had an anaphylactic reaction with the first dose of **Abdala ST**.

Persons with chronic diseases, autoimmune or endocrine-metabolic diseases must have the illness compensated at the time of vaccination. The measurement of vital signs before vaccination is recommended; in the case of arterial hypertension, we suggest that the immunization should be delayed until there is evidence that the blood pressure is controlled.

In individuals that report having an acute infection within the last 15 days, the inoculation with **Abdala ST** should be postponed until the infection is resolved.

The convalescents from COVID-19 must follow the vaccination protocol approved for those cases.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

We recommend the visual inspection of the vial before its administration. The vial must not be used if there is evidence that its physical integrity has been tampered (the container-closure system) or if there are changes in the physical properties of the suspension (color, transparency, presence of particles, precipitates).

Shake before use.

It must not be administered intravenously.

UNDESIRABLE EFFECTS

Clinical experience shows that after the application of the **Abdala ST** vaccine in adults, adverse events are mild (97 %), and spontaneously disappear without any pharmacological treatment. They mainly occur during the first 24 to 48 hours after vaccination.

The frequency of adverse events is greater after the application of the first dose within the vaccination schedule, and it decreases after the application of the following doses.

The safety profile evaluated was confirmed after the application of 215 267 doses in the clinical intervention trial in cohorts at risk.

The frequency of the presence of adverse events is low, of 0.1 to 1 % of all doses applied; they are basically local, with a predominance of pain at the vaccination site, as well as erythema and induration (0.85 %).

The systemic adverse reactions include headache (0.54 %), arterial hypertension (0.27 %), sleepiness (0.18 %) and asthenia (0.14 %).

Data continue to be collected to determine the causal relationship between the application of the vaccine and arterial hypertension, since its occurrence depends on multiple factors, and in clinical studies with this product, the frequency of this adverse event was similar to that observed in the control group (placebo).

Other adverse reactions were reported with a frequency of less than 0.1 % of all doses applied. These include nausea, vomiting, arthralgia and general discomfort.

After the application of more than three million doses in the health intervention in populations and territories at risk, we have recorded anaphylaxis at a frequency of 0.19 per 100 000 doses applied, which is considered to be very rare (< 1/10 000). No other severe adverse reactions have been found. No deaths associated to the vaccination with **Abdala ST** have been recorded.

DOSAGE AND MODE OF ADMINISTRATION

Dosage and administration schedule:

A dose of 0.5 mL of the **Abdala ST** vaccine must be administered.

The schedule used is of three doses with an interval of 14 days between doses.

Administration route:

Abdala ST is administered by an intramuscular injection at the deltoid region of the arm, using needles of 23G or 22G x 25 mm.

It should never be administered through endovenous injections.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

We do not have information on the interaction of **Abdala ST** with other vaccines.

Immunosuppressive therapy may interfere with the vaccine response.

USE DURING PREGNANCY AND WHEN LACTATING

Our experience with the use of this vaccine in pregnant women is limited. Studies in animals do not suggest any direct or indirect harmful effects during pregnancy in the development of the embryo or fetus, or during birth or post-natal development. The administration of **Abdala ST** during pregnancy should only be considered if the possible benefits are higher than the risks for the mother and the fetus.

There is not enough evidence of any contraindication for its use in women who are lactating.

STORAGE CONDITIONS

Store at 2 to 8 °C. DO NOT FREEZE

PRESENTATION

Box for 25 vials containing 0.5 mL each

Text revised and updated: August, 2021

BI-21-075-LI

CIGB CENTRO DE INGENIERÍA GENÉTICA Y BIOTECNOLOGÍA

Produced and commercialized by the Center for Genetic Engineering and Biotechnology
Ave. 31 e/ 158 y 190, Cubanacán, Playa
La Habana, Cuba
C.P. 11600