FACT SHEET FOR VACCINE RECIPIENTS AND CAREGIVERS APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION IN PUBLIC INTEREST

THE BIOLOGICAL E. LIMITED, SARS-CoV-2 (Covid-19) Vaccine

CORBEVAX®

IN PREVENTION OF COVID-19 DISEASE IN INDIVIDUALS AGED 5 YEARS AND ABOVE

This vaccine has been approved for restricted use in emergency situation. It does not have a marketing authorization, however, this approval for the restricted use in emergency situation grants permission for the vaccine to be used for active immunization in individuals aged 5 years and above for the prevention of coronavirus disease 2019 (COVID-19). **CORBEVAX®** is also indicated as a booster dose at ≥ 6 months after completion of primary immunization with 2 doses of Covishield™ or Covaxin® in individuals aged 18 years and above.

Reporting of Side Effects

As with any new medicine, this vaccine will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects, you may get after vaccination to the Biological E. Limited (BE) who is the manufacturer of CORBEVAX® on 24x7 Toll-Free Number: 1800 309 0150 or at pharmacovigilance@biologicale.com. For more information, read this fact sheet carefully.

You are being offered the SARS-CoV-2 (Covid-19) Vaccine [**CORBEVAX®**] of Biological E. Limited to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the **CORBEVAX®**.

The **CORBEVAX®** is a vaccine and may prevent you from getting COVID-19 disease.

Read this Fact Sheet for information about the **CORBEVAX®** Talk to the vaccinator / healthcare provider if you have questions. It is your choice to receive the Biological E. Limited Covid-19 Vaccine [**CORBEVAX®**]

The **CORBEVAX®** vaccination course consists of two separate doses of 0.5 mL each. The second dose should be administered at least 4 weeks after the first dose.

CORBEVAX® can also be administered as a booster dose in individuals aged 18 years and above at ≥6 months after completion of primary immunization with 2 doses of Covishield™ or Covaxin®.

After the vaccine is administered, **the vaccinee should be monitored by a healthcare professional for 30 minutes.** The vaccine should be administered by intramuscular (IM) injection only. The **CORBEVAX®** may not protect everyone.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhoea.

WHAT IS THE BE's CORBEVAX® VACCINE?

CORBEVAX® is a protein sub-unit vaccine, developed from a component of the spike protein on the virus's surface, which helps the body build the immune response against the virus.

The vaccine has the Receptor Binding Domain (RBD) protein as an antigen, CpG 1018 and Aluminium hydroxide as adjuvants formulated in Tris buffer.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER BEFORE YOU GET CORBEVAX® VACCINE?

- Tell the healthcare provider/Doctor about all of your medical conditions, including:
- If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of **CORBEVAX®**
- If you have fever or severe infection
- If you have a bleeding disorder or are on a blood thinner
- If you are immunocompromised or are on a medicine that affects your immune system
- If you are pregnant or plan to become pregnant and lactating women
- If you have received another COVID-19 vaccine

If you have any of the above conditions, you should consult your healthcare provider/Doctor before deciding to take the vaccine.

WHO SHOULD GET THE CORBEVAX® VACCINE?

CORBEVAX® has been approved for restricted use in emergency situation in individuals aged 5 years and above. **CORBEVAX®** can also be administered as a booster dose in individuals aged 18 years and above at ≥6 months after completion of primary immunization with 2 doses of Covishield™ or Covaxin®.

WHO SHOULD NOT GET THE CORBEVAX® VACCINE?

You should not get the **CORBEVAX®** if you:

- Had a severe allergic reaction after a previous dose of this vaccine
- Hypersensitivity to any component of a vaccine or a vaccine containing similar components
- History of severe allergic reactions
- If you are suffering from common cold, runny nose, fever, cough, body ache or loose motions etc
- Pregnancy and the period of lactation
- Individuals aged below 5 years

WHAT ARE THE INGREDIENTS IN THE CORBEVAX® VACCINE?

The **CORBEVAX®** includes the following ingredients:

- Aluminium Hydroxide gel as Al^{+++}
- CpG 1018
- Buffer (Tris and NaCl in WFI)

HOW IS THE CORBEVAX® GIVEN?

The **CORBEVAX®** will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle. The **CORBEVAX®** vaccination course consists of two separate doses of 0.5 mL each.

If you receive one dose of the **CORBEVAX®** then the second dose should be administered at least 4 weeks after the first dose. **After the vaccine is administered, you will be monitored by a healthcare professional for 30 minutes.**

If you miss your second dose;

If you forget to go back at the scheduled time, ask your healthcare provider/Doctor for advice.

It is important that you return for your second dose of **CORBEVAX®**

CORBEVAX® can also be administered as a booster dose in individuals aged 18 years and above at ≥6 months after completion of primary immunization with 2 doses of Covishield™ or Covaxin®.

HAS THE CORBEVAX® BEEN USED BEFORE?

The **CORBEVAX®** is used in clinical trials, a number of participants received one or two doses in Indian trials. The vaccine is also being used in individuals aged 12 years to 14 years as part of immunization in India.

WHAT ARE THE BENEFITS OF THE CORBEVAX® VACCINE?

In clinical trials, the **CORBEVAX®** has been shown to prevent COVID-19 disease following 2 doses given at 4 weeks' interval. The duration of protection against COVID-19 disease is currently unknown. You may get protective immune response 2 weeks after the second dose of **CORBEVAX®**.

It is important to appreciate that receiving the vaccine does not mean that other precautions related to COVID-19 need not be followed. All Covid-19 precautions such as maintaining physical distance from others, wearing mask in public and cleaning your hands frequently with alcohol-based hand rub or soap and water need to followed even after receiving the vaccine dose.

WHAT ARE THE RISKS OF THE CORBEVAX® VACCINE?

Side effects that have been reported with the **CORBEVAX®** include:
Systemic:

Common (may affect up to 1 in 10 people)

- Fever/Pyrexia
- Headache
- Fatigue
- Body pain
- Myalgia
- Nausea

Uncommon (may affect up to 1 in 100 people)

- Arthralgia
- Urticaria
- Chills
- Lethargy

Local:

Very common (may affect up to ≥1 in 10 people)

- Injection site pain

Common (may affect up to 1 in 10 people)

- Injection site erythema

Uncommon (may affect up to 1 in 100 people)

- Injection site swelling
- Injection site rash
- Injection site pruritus

Rare (may affect up to 1 in 1000 people)

- Injection site irritation

These may not be all the possible side effects of the **CORBEVAX®** Serious and unexpected side effects may occur. If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider / doctor.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call or go to the nearest hospital. Call the healthcare provider if you have any side effects that bother you or do not go away.
In addition, you can report side effects after vaccination to Biological E. Limited, who is the manufacturer of **CORBEVAX®** as below.

- 24x7 Toll-free Number (For Medical and Adverse Event Related Queries Only): 1800 309 0150 or pharmacovigilance@biologicale.com.

All adverse events reported will be entered in COWIN App by the health care provider.

WHAT IF I DECIDE NOT TO GET THE CORBEVAX® VACCINE?

It is your choice to receive or not receive the **CORBEVAX®**. You may prefer to consult your healthcare provider.

CAN I RECEIVE THE CORBEVAX® VACCINE WITH OTHER VACCINES?

There is no information on the use of the **CORBEVAX®** with other vaccines.

CAN CORBEVAX® VACCINE BE GIVEN AS A BOOSTER DOSE?

Yes. The **CORBEVAX®** can be administered as a booster dose in individuals aged 18 years and above at ≥6 months after completion of primary immunization with 2 doses of Covishield™ or Covaxin®.

The Phase III clinical trials conducted with **CORBEVAX®** as a booster dose showed significant increase in neutralizing antibodies (PRNT50) in individuals who completed primary immunization with 2 doses of Covishield™ or Covaxin®.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

You may discuss your options with the healthcare provider/Doctor.

WILL THE CORBEVAX® VACCINE GIVE ME COVID-19 INFECTION?

No. The **CORBEVAX®** COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19 infection.

KEEP YOUR VACCINATION CARD

When you get your dose, please discuss with your healthcare provider regarding the option of your vaccination record on digital platform, if available.

HOW CAN I LEARN MORE?

- Ask the healthcare provider/Doctor.
- Consult your local or state public health department.

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