

Coviran Barkat[®]

COVID-19 Vaccine



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Coviran Barkat[®] as an approved vaccine by Iran Food and Drug Administration (IFDA) against COVID-19 virus, contains 5µg inactivated purified virus as the immunogenic antigen per each dose. In manufacturing process of Coviran Barkat[®] vaccine, the virus is propagated in Vero cells followed by inactivation, purification and finally, formulation with aluminum hydroxide as adjuvant. Coviran Barkat[®] vaccine is provided in both single and multi-dose (10 doses) vials. This vaccine is manufactured and tested according to World Health Organization (WHO) requirements. The vaccine stimulates the immune system to induce antibodies as well as cellular immunity response against the SARS COV-2, as causative agent of Covid-19 infection.

Vaccine composition

Each dose of Coviran Barkat[®] vaccine contains active ingredient, excipient and solvent as following table

Composition	Content	Function
Inactivated, purified virus	5 µg	Active ingredient and stimulation of immune system
Aluminum hydroxide	250 µg	Enhancement of immune response - Adjuvant
PBS	qs	Solvent

Dosage form

Coviran Barkat[®] vaccine is prepared in a sterile suspension for intramuscular injection only. The vaccine is manufactured and available in single and ten doses vials.

Indications

Coviran Barkat[®] vaccine induces immunity against Covid-19 by stimulation of strong and stable immune response and boosting immune system, which results in antibody production in the vaccinee. In some elder and people with weakened immune systems, less efficacy may be results. The vaccine is administered as two doses with 4 weeks intervals. In 2 to 6 weeks after receiving the second dose of the vaccine, the best immune response will be achieved. However, the precious protecting duration of the vaccine is still unknown and more data should be collected. The safety and immunogenicity of this product has been evaluated in people older than 18 years old and should be administered to these age groups only.

Dosage and Administration

Two doses of Coviran Barkat[®] vaccine with four weeks interval results in the highest immunity in the population at 18 years and above. Each dose of the vaccine contains 0.5 ml whitish suspension, which must be injected intramuscularly. There is no difference between the first and the second dose of the vaccine.

Coviran Barkat[®] vaccine must only be administrated intramuscularly (in deltoid muscle, outside portion of upper arm muscle on the non-dominant hand). Do not administer subcutaneously or intravenously.

Coviran Barkat[®] vaccine must not be mixed with any other vaccine or medicine before injection.

There is not enough clinical data available by this time for using this vaccine in people under the age of 18, pregnant and breastfeeding women.

Direction for use

Shake gently the Coviran Barkat[®] vaccine vial before use to obtain a homogeneous suspension. Apply 1 or 2 ml syringe with gauge 25 needle for injection. Attention should be paid to extraction of one dose (0.5 ml) in to the syringe. The alcohol pad should be used to disinfect the site of injection before administration of the vaccine.

Contra indication

According to studies, Coviran Barkat[®] vaccine must be only used in 18 years old and above. Administration of this vaccine to ages bellow 18 is not allowed. Due to limited available information, the injection of this vaccine is not recommended in symptomatic SARS-CoV-2 infected people (positive PCR test, fever, chills, abdominal pain, diarrhea, etc.) until complete recovery. Patients with hemophilia, thrombocytopenia and patients under treatment with anticoagulants (Warfarin, Dabigatran, Rivaroxaban, Enoxaparin, Dalteparin, and Heparin) may experience subcutaneous bleeding after intramuscular vaccine injection. In these cases, consult your physician before receiving the vaccine.

In the case of any severe symptoms and allergies (such as high fever above 39°C, seizures, severe allergic reactions or anaphylaxis) following injection of the first dose of the vaccine, administration of the second dose must be avoided and needs to be consulted with a physician.

Warning

Due to the pandemic situation and highly contagious nature of the virus, all recommended preventive measures and protocols must fully considered and applied even after vaccination.

The longevity of protecting antibody levels following vaccination with Coviran Barkat[®] has been shown for up to 6 months. However, more studies are in progress to determine the maximum duration of immunity after injection of the second dose.

Subcutaneous or intravascular injection of the vaccine is strictly prohibited.

Vaccination should be done in special medical centers, where anaphylactic shock medications (such as epinephrine) are available to treat any acute adverse reaction.

Vaccinated people should be stayed and followed up in the vaccination site for up to 15 minutes after injection.

For people with high fever or common cold symptoms, Coviran Barkat[®] vaccine administration is not recommended and should be postponed till fully disappearing of the symptoms.

Precautions

Separate sterile syringe must be used for each person.

Caution should be considered in the case of observation of any coagulation abnormalities or decrease in blood platelets. People with weakened immune systems or those who are under treatment of immunosuppressive drugs (such as cancer on chemotherapy) may not show strong immune response against vaccine. Although, the immune response may be lower than expected in people with chronic weakened immune systems, vaccination with Coviran Barkat[®] vaccine is recommended.

Drug interactions

Chloroquine, Corticosteroids and analgesics may reduce the antibody levels which compromises the effectiveness of the vaccine. Drug interactions have not yet been evaluated in the cases of uncontrolled epilepsy or progressive neurological diseases.

Adverse Reactions

Results from clinical trials suggest that side effects following the first and second dose of the vaccine injection are generally mild to moderate and is recovered in 1-2 days after injection. The most common side effects are similar to mild flu illness (fever, chills, muscle and joint pain, sore throat, nasal congestion, weakness, malaise and headache), pain, swelling and redness at site of injection. These side effects usually recover without any medication but painkillers such as acetaminophen can be used to reduce pain and fever. According to clinical trials reports, no severe side effects have been observed to date.

Storage

Coviran Barkat[®] vaccine should be stored and transported at 2 to 8 °C. Do not freeze.

In the case of observation of freeze content, do not use the vaccine. Opened vials should be use within 8 hours and should be kept at 2-8°C during this period and should be discarded after 8 hours.



Manufacturer
Shifa Pharmed Industrial Group
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