FACT SHEET FOR VACCINE RECIPIENT

APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION
OF
ChAdOx1 nCoV- 19 CORONA VIRUS VACCINE (RECOMBINANT)

COVISHIELD™

IN PREVENTION OF (COVID-19) DISEASE

IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

This vaccine has been given restricted use license for 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 of individuals aged 18 years and older for the prevention of coronavirus disease 2019 (COVID-19).

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 Serum Institute of India Pvt Ltd who is the manufacturer of COVISHIELD™ vaccine on 24 x 7 Toll-Free Number: 1800 1200124 or at pharmacovigilance@seruminstitute.com.
For more information read this fact sheet carefully.

You are being offered the Serum Institute of India Pvt. Ltd. (SIIPL) COVISHIELD™ Vaccine 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 COVISHIELD™ Vaccine, which you may receive because there is currently a pandemic of COVID-19 disease.

The COVISHIELD™ is a vaccine and may prevent you from getting COVID-19 disease.

Read this Fact Sheet for information about the COVISHIELD™ Vaccine. Talk to the

The COVISHIELD™ 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; diarrhea.

WHAT IS THE SIIPL COVISHIELD™ VACCINE?

The COVISHIELD™ vaccine is approved for restricted use in emergency situation that may prevent COVID-19 disease in individuals 18 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER / DOCTOR BEFORE YOU GET COVISHIELD™ 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 COVISHIELD™ vaccine
- If you have ever had a blood clot or low blood platelets (thrombocytopenia) in the past
- If you have fever
- If you have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant)
- If your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines)
- If you are pregnant or plan to become pregnant
- If you are breastfeeding

medicine (anticoagulant) because bleeding or bruising may occur following an intramuscular injection in these individuals.

A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination in such individuals, followed by firm pressure on the injection site, without rubbing, for at least 2 minutes. The patient or family should be given information on the risk for hematoma from the injection. Patients receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for intramuscular administration. If possible, vaccination could be scheduled prior to the use of these medications, so that the patients' risk of bleeding is not increased by their therapeutic action.

Blood disorders:
Very rare cases of blood clots with low levels of blood platelets have been observed following vaccination with ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant). The majority of these cases occurred within the first 14 days following vaccination and some cases had a fatal outcome.

Seek urgent medical attention if from a few days following vaccination you get any of the following symptoms:

- experience a severe or persistent headache, blurred vision, confusion or seizures (fits)
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination

Patients with weak immune system or receiving immunosuppressive medicines:
No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses. People with weakened immune systems due to other illnesses or medications might be at increased risk for severe COVID-19. They may receive COVISHIELD™. However, they should be aware of that safety of COVISHIELD™ for people who have weakened immune systems is not yet available. People with weakened immune systems should also be aware of the potential for reduced immune responses to COVISHIELD™, as well as the need to continue following all current guidance to protect themselves

WHO SHOULD NOT GET THE COVISHIELD™ VACCINE?

You should not get the COVISHIELD™ Vaccine:

1. If you have ever had a serious allergic reaction (including anaphylaxis) to:
    - a previous dose of COVISHIELD™
    - any ingredient of COVISHIELD™ (listed below).
2. If you have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine should not receive a second dose of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant).
3. If you had ever had a condition known as heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2).

If you are not sure, talk to your doctor, pharmacist or nurse.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It can be life-threatening.

People with a history of severe allergic reactions not related to vaccines or injectable medications such as food, pets, environmental, or latex allergies may get vaccinated. People with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated.

WHAT ARE THE INGREDIENTS IN THE COVISHIELD™ VACCINE?

The COVISHIELD™ Vaccine includes the following ingredients:

L-Histidine
L-Histidine hydrochloride monohydrate
Magnesium chloride hexahydrate
Polysorbate 80
Ethanol
Sucrose
Sodium chloride
Disodium edetate dihydrate (EDTA)

If you receive one dose of the COVISHIELD™ vaccine, then the second dose should be administered between 4 to 12 weeks after the first dose.

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 COVISHIELD™ vaccine.

HAS THE COVISHIELD™ VACCINE BEEN USED BEFORE?

The **COVISHIELD™** is used in clinical trials, a number of participants received one or two doses in overseas and Indian trials.

WHAT ARE THE BENEFITS OF THE COVISHIELD™ VACCINE?

In ongoing clinical trials, the **COVISHIELD™** Vaccine has been shown to prevent COVID-19 disease following 2 doses given between 4 and 12 weeks apart. The duration of protection against COVID-19 disease is currently unknown.

Protection against COVID-19 disease starts from approximately 3 weeks after the first dose of COVISHIELD™. Individuals may not be fully protected until 15 days after the second dose is administered. However, please note that as with any vaccine, COVISHIELD™ may not protect everyone who is vaccinated from COVID-19. Therefore, you should follow all the standard measures listed below.

It is not yet known how long people who receive the vaccine will be protected.

WHAT ARE THE RISKS OF THE COVISHIELD™ VACCINE?

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Get urgent medical attention from your doctor if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath or wheezing
- swelling of your lips, face, or throat

Very Common (may affect more than 1 in 10 people)

- tenderness, pain, warmth, or itching where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache
- feeling sick (nausea)
- joint pain or muscle ache

Common (may affect up to 1 in 10 people)

- swelling or redness where the injection is given
- fever
- being sick (vomiting) or diarrhea
- pain in legs or arms
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Uncommon (may affect up to 1 in 100 people)

- sleepiness or feeling dizzy
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin, rash or hives

Very rare

- major blood clots in combination with low levels of blood platelets (thrombocytopenia) have been observed with a frequency of less than 1 in 100,000 vaccinated individuals.

Not known (the frequency cannot be determined from the available data)

- severe allergic reaction (anaphylaxis)
- severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing)

Most of the side effects with COVISHIELD™ occur on the day of vaccination and are uncommon by Day 5 to 7, indicating that these effects are self-limiting and of short duration. The majority of the side effects are mild or moderate in severity. When

These may not be all the possible side effects of the COVISHIELD™ Vaccine. Serious and unexpected side effects may occur. If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider / doctor. **COVISHIELD™ Vaccine is still being studied in clinical trials.**

If you experience unusually high or prolonged fever, or other symptoms, alternative causes should be considered and contact your healthcare provider / doctor to seek further medical advice .

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 / doctor if you have any side effects that bother you or do not go away.

In addition, you can report side effects after vaccination to Serum Institute of India Pvt Ltd who is the manufacturer of COVISHIELD™ vaccine as below:

- 24x7 Call Center Toll-Free Number **(For Reporting of Adverse Events Only)**: 1800 1200124
- pharmacovigilance@seruminstitute.com

WHAT IF I DECIDE NOT TO GET THE COVISHIELD™ VACCINE?

It is your choice to receive or not receive the COVISHIELD™ Vaccine. You may prefer to consult your healthcare provider / doctor.

CAN I RECEIVE THE COVISHIELD™ VACCINE WITH OTHER VACCINES?

There is no information on the use of the COVISHIELD™ Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

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

WILL THE COVISHIELD™ VACCINE GIVE ME COVID-19 INFECTION?

No. The COVISHIELD™ COVID-19 Vaccine does not contain SARS-CoV-2 and cannot

AFTER VACCINATION, DO I NEED TO CONTINUE TAKING PRECAUTIONS TO PREVENT COVID-19 INFECTION?

People who get vaccinated should continue to follow all current guidance to protect themselves against COVID-19 after they are vaccinated. That means:

- Wearing a mask
- Staying at least six feet away from others
- Avoiding crowds
- Washing hands with soap and water or using hand sanitizer

HOW CAN I LEARN MORE?

- Ask the healthcare provider / doctor.
- Contact your local or state public health department.

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