

SII

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: +91-1800 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 healthcare provider if you have questions. It is your choice to receive the COVISHIELD™ Vaccine.

The COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.

For intramuscular (IM) injection only.

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

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER BEFORE YOU GET COVISHIELD™ VACCINE?

Tell the healthcare provider 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 fever
- 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
- If you are breastfeeding
- If you have received another COVID-19 vaccine

You should consult your healthcare provider before deciding to take the vaccine.

WHO SHOULD GET THE COVISHIELD™ VACCINE?

COVISHIELD™ Vaccine has been approved for restricted use in emergency situation in individuals 18 years of age and older.

WHO SHOULD NOT GET THE COVISHIELD™ VACCINE?

You should not get the COVISHIELD™ Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

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), Water for injection.

HOW IS THE COVISHIELD™ GIVEN?

The COVISHIELD™ Vaccine will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle.

The COVISHIELD™ vaccination course consists of two separate doses of 0.5 ml each.

If you receive one dose of the COVISHIELD™ vaccine, then the second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.

If you miss your second dose

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

You may get protective immune response 4 weeks after the second dose of COVISHIELD™ vaccine.

WHAT ARE THE RISKS OF THE COVISHIELD™ VACCINE?

Side effects that have been reported with the COVISHIELD™ Vaccine include:

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

- tenderness, pain, warmth, redness, itching, swelling or bruising 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)

- a lump at the injection site
- fever
- being sick (vomiting)
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Uncommon (may affect up to 1 in 100 people)

- feeling dizzy
- decreased appetite
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin or rash

These may not be all the possible side effects of the COVISHIELD™ Vaccine. Serious and unexpected side effects may occur. COVISHIELD™ Vaccine is still being studied in clinical trials.

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 Serum Institute of India Pvt Ltd who is the manufacturer of COVISHIELD™ vaccine as below.

- 24 x 7 Call Center Toll-Free Number (For Medical and Adverse Event Related Queries Only): +91-1800 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.

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.

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

No. The COVISHIELD™ 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.
- Contact your local or state public health department.

Revised: 01 January 2021



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