

FACT SHEET FOR VACCINE RECIPIENT
APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION OF
Novel Corona Virus 2019 - nCoV Vaccine (Recombinant)



**IN PREVENTION OF COVID-19 DISEASE
IN INDIVIDUALS 12 YEARS OF AGE AND OLDER**

You are being offered ZyCoV-D® Vaccine of Cadila Healthcare Ltd 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 ZyCoV-D® Vaccine, which you may receive because there is currently a pandemic of COVID-19 disease.

ZyCoV-D® is a vaccine and may prevent you from getting COVID-19 disease. ZyCoV-D® vaccination course consists of three separate doses of 0.2 ml each.

ZyCoV-D® vaccination schedule consists of 3 separate doses of 2mg each to be given at an interval of 28 days each (day 0, day 28 and day 56). Each 2mg dose consists of two shots of 0.1ml each given by needle free injector (Pharmajet Tropis device) via intradermal route at two separate sites (preferably deltoid region of both the arms).

ZyCoV-D® vaccine has shown efficacy of 66.6% in interim analysis. This vaccine 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 ZyCoV-D® VACCINE?

ZyCoV-D® is approved for restricted use in emergency situation vaccine that may prevent COVID-19 disease in individuals 12 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER BEFORE YOU GET ZyCoV-D® 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 ZyCoV-D® 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 ZyCoV-D® VACCINE?

ZyCoV-D® Vaccine has been approved for restricted use in emergency situation in individuals 12 years of age and older.

WHO SHOULD NOT GET ZyCoV-D® VACCINE?

You should not get ZyCoV-D® 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
- had a severe allergic reaction to any other vaccine

WHAT ARE THE INGREDIENTS IN ZyCoV-D® VACCINE?

ZyCoV-D® Vaccine includes the following ingredients:

Deoxyribonucleic acid (DNA)

Phosphate buffered saline

HOW IS ZyCoV-D® GIVEN?

ZyCoV-D® Vaccine will be given to you as an Intradermal (ID) injection only using Needle Free Injector (Pharmajet Tropis device).

ZyCoV-D® vaccination course consists of three separate doses of 2mg each.

If you receive one dose of ZyCoV-D® vaccine, then the 2nd / 3rd dose should be administered 28 days after the previous dose.

If you miss your 2nd / 3rd 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 2nd & 3rd dose of ZyCoV-D® vaccine.

HAS ZyCoV-D® VACCINE BEEN USED BEFORE?

ZyCoV-D® is being used in clinical trials, a number of participants have received one or two or three doses in trials being conducted in India.

WHAT ARE THE BENEFITS OF ZyCoV-D® VACCINE?

In ongoing clinical trials, ZyCoV-D® Vaccine has been shown to prevent COVID-19 disease following 3 doses of 2mg each given 28 days apart. The duration of protection against COVID-19 disease is currently unknown.

You may get protective immune response 28 days after the 3rd dose of ZyCoV-D® vaccine.

WHAT ARE THE RISKS OF ZyCoV-D® VACCINE?

Common side effects that have been reported with ZyCoV-D® Vaccine include:

- Injection site redness
- Injection site pain
- Injection site itching
- Injection site swelling
- Fever
- Muscle Pain
- Headache
- Nausea
- Fatigue / Tiredness
- Diarrhea

These may not be all the possible side effects of ZyCoV-D® Vaccine. Serious and unexpected side effects may occur. ZyCoV-D® 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 Cadila Healthcare Limited who is the manufacturer of ZyCoV-D® vaccine on toll free number 1800 419 1141 or visit www.zyducadila.com

WHAT IF I DECIDE NOT TO GET ZyCoV-D® VACCINE?

It is your choice to receive or not receive ZyCoV-D® Vaccine. You may prefer to consult your healthcare provider.

CAN I RECEIVE ZyCoV-D® VACCINE WITH OTHER VACCINES?

There is no information on the use of ZyCoV-D® Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is no clinical data on use of ZyCoV-D® Vaccine in pregnant and breastfeeding women. You may discuss your options with the healthcare provider.

WILL ZyCoV-D® VACCINE GIVE ME COVID-19 INFECTION?

No. ZyCoV-D® Vaccine does not contain SARS-CoV-2 virus 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.
- For further details on vaccine and answers to frequently asked questions, kindly visit www.zycovd.co.in

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