INFORMATION FOR THE PATIENT

COVID-19 VACCINE ASTRAZENECA, SOLUTION FOR INJECTION (IM)

COVID-19 Vaccine (ChAdOx1-S [recombinant])

WHAT IS COVID-19 DISEASE?

COVID-19 is   a viral disease that mainly affects respiratory system but may also affects the other organs such as the heart, kidney, blood vessels etc. People above 60 years of age and those with underlying conditions such as heart, lung, liver, kidney diseases, those with immunocompromised state, diabetes, pregnancies etc. may have more severe presentation and outcome.

SARS-Cov-2 is highly infectious and can be transmitted through respiratory route and by contact. A person may develop symptoms within 1 to 14 days after exposure. Person can transmit the virus 2 days before the symptom onset and up to 10 days after symptom onset or more, depending on severity of presentation and immune status. About 40% of people may not develop any symptoms though they are able to transmit the infection. Common symptoms include, sore throat, runny nose, cough, fever, shortness of breath, headache, body ache, loss of smell/taste, diarrhoea, and vomiting.

If a person develops COVID-19 like symptoms, they should self-isolate and visit a flu clinic and get tested. COVID-19 PCR test can detect the infection.

To minimize the chance of catching the virus, it is advisable to follow all preventive measures such as wearing masks, physical distancing (at least 3 feet distance), frequent hand washing, cleaning and disinfection of surfaces and ensure good ventilation of premises.

WHAT ARE THE BENEFITS OF VACCINATION?

Vaccination protects the person taking the vaccine and the community. When more people are vaccinated it prevents community transmission and protects those who cannot take the vaccine like young children etc. Two doses of vaccine are required to attain full protection.

The vaccine decreases development of severe COVID-19 disease and will decrease risk of hospitalization and also help in reducing spread of Covid-19 disease. However, there may be a chance that you might still get or spread infection even after vaccination. Therefore, it is important to wear mask and follow the social distancing guidance and other preventive measures.

WHAT COVID-19 VACCINE ASTRAZENECA IS AND WHAT IT IS USED FOR

COVID-19 Vaccine AstraZeneca is a vaccine used to protect people aged 18 years and older against COVID-19.

COVID-19 is caused by a virus called coronavirus (SARS-CoV-2).

COVID-19 Vaccine AstraZeneca stimulates the body's natural defenses (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect you against COVID-19 in the future. None of the ingredients in this vaccine can cause COVID-19.

WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE COVID-19 VACCINE ASTRAZENECA?

Do not have the vaccine:

- If you are under the age of 18 years
- If you have a history of a significant allergic reaction to any previous dose of the vaccine
- If you have history of an allergic reaction to any component of the vaccine (L- Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate (EDTA))
- If you are pregnant
- Who is acutely unwell with or without fever till symptoms are resolved
- Individuals who have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with COVID-19 Vaccine AstraZeneca/Covishield vaccine
- If you have history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type II) or cerebral venous sinus thrombosis.

If you are not sure, talk to your healthcare provider.

Warnings and precautions

Tell your healthcare provider before vaccination:

- If you have ever had a severe allergic reaction after any other vaccine injection or after you were given COVID-19 Vaccine AstraZeneca in the past;
- If you currently have are currently unwell with or without fever
- If you have ever had a blood clot or low blood platelets (thrombocytopenia) in the past;
- 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 are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines).
- If you have developed COVID-19 in the past 28 days
- If you have been in contact with a COVID-19 positive case within past 14 days

If you are not sure if any of the above applies to you, talk to your healthcare provider before you are given the vaccine.

As with any vaccine, COVID-19 Vaccine AstraZeneca may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected.

Children and adolescents

No data are currently available on the use of COVID-19 Vaccine AstraZeneca in children and adolescents younger than 18 years of age.

Other medicines and COVID-19 Vaccine AstraZeneca

Tell your healthcare provider if you are taking, have recently taken or might take, any other medicines or vaccines.

Pregnancy and breastfeeding

If you are pregnant do not take AstraZeneca vaccine.

Those who are breastfeeding may take AstraZeneca vaccine.

Driving and using machines

COVID-19 Vaccine AstraZeneca has no known effect on the ability to drive and use machines. However, side effects listed in may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines

HOW COVID-19 VACCINE ASTRAZENECA IS GIVEN

COVID-19 Vaccine AstraZeneca is injected into a muscle (usually in the upper arm).

You will receive 2 injections. You will be told when you need to return for your second injection of COVID-19 Vaccine AstraZeneca.

The recommended dosage is 2 doses given intramuscularly (0.5ml each) with an interval of 8 to 12 weeks. However, the second dose can be given a minimum interval of 4 weeks after 1st dose of vaccine.

When COVID-19 Vaccine AstraZeneca is given for the first injection, COVID-19 Vaccine

AstraZeneca (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course unless specified by the National immunization Program.

If you miss an injection

It is important that you return for your second injection of COVID-19 Vaccine AstraZeneca. Even if you miss a dose it is recommended to get the dose as soon as possible. If the duration is more than 3 months in between doses inform the health care provider.

POSSIBLE SIDE EFFECTS

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

Get medical attention immediately 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

Get urgent medical attention 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

In clinical studies, most side effects were mild to moderate in nature and resolved within a few days. Fewer side effects were reported after the second dose.

Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.

After vaccination, you may have more than one side effect at the same time (for example, muscle/joint aches, headaches, chills and generally feeling unwell). If any of your symptoms are persistent, please seek advice from your healthcare provider.

THE FOLLOWING SIDE EFFECTS MAY OCCUR WITH COVID-19 VACCINE ASTRAZENECA:

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 diarrhoea
- 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)

If you notice any side effects, including side effects not mentioned in this information sheet, please inform your healthcare provider.

Note: If you have any queries regarding Covid-19 vaccine, please email to vaccine@health.gov.mv

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