COVISHIELD: ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant)

COVISHIELD vaccine for covid-19 contains ChAdOx1 nCoV-19 corona virus vaccine (Recombinant) 5x10 ^10 virus particles
*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein produced in genetically modified human embryonic kidney (HEK) 293 cells. Both COVISHIELD manufactured by Serum institute of India and covid -19 vaccine Astrazeneca manufactured by Astrazeneca are ChAdOx1 nCoV-19 corona virus vaccines (Recombinant).

Pharmacological form

This vaccine is available as a solution for injection. It is colorless to slightly brown, clear to slightly opaque and particle free with a pH of 6.6.

Clinical information

Therapeutic indications

COVISHIELD is indicated for active immunization of individuals more than 18 years old for the prevention of coronavirus disease 2019 (Covid-19).

Posology and method of administration

COVISHIELD vaccination course consists of two separate doses of 0.5 mls each. The second dose should be administered between 4-6 weeks after the first dose. However there is data available for administration of the second dose of the vaccine up to 12 weeks after the first dose.

It is recommended that individuals who receive a first dose of COVISHIELD vaccine to complete the vaccination course with COVISHIELD .

Special populations

Elderly population: Efficacy and safety is currently limited to individuals greater than or equal to 65 years old. No dosage adjustment is required in elderly individuals with more than 65 years.

Pediatric population: The safety and efficacy of COVISHIELD for pediatrics and adolescents less than 18 years old has not been established yet. No data is available yet.

Method of administration

COVISHIELD is for intramuscular administration preferably on the deltoid muscle.

Contraindications

Hypersensitivity to the active substance or to any of the excipients of the vaccine.

Special warnings and precautions

Hypersensitivity
As with other vaccines, appropriate medical treatment and supervision should be always be readily available in case of an anaphylactic reaction event following the administration of the above vaccine.

Concurrent illness

As with other intramuscular injections, COVISHIELD vaccines should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection such as a cold and or low-grade fever should not delay vaccination.

Thrombocytopenia **and coagulation disorders**

As with intramuscular injections, COVISHIELD should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulant therapy, because bleeding or bruising may occur following an intramuscular administration in these people.

Immunocompromised patients.

It is not known whether individuals with impaired immune responsiveness including individuals receiving immunosuppresant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.
Immunocompromised individuals may have a relatively weaker immune response to the vaccine regimen.

Duration and level of protection

The duration of protection has not yet been established
As with any vaccine, vaccination with COVISHIELD may not protect all the vaccine recipients,

Interchangeability

No data available on the use of ChAdOx1 nCoV-19 corona virus vaccine (Recombinant) in persons that have previously received partial series with another COVID-19 Vaccine.

Interaction with other medical products and other forms of interaction.

No interaction studies have been performed yet
Concomitant administration of COVISHIELD with other vaccines has not been studied.

Fertility and pregnancy

Preliminary animal studies do not indicate any direct or indirect harmful effects with the respect to fertility.

Pregnancy

There is limited data and experience with the use of COVISHIELD in pregnant women. Preliminary animal studies do not indicate any direct or indirect harmful effects in relation to pregnancy, embryo-fetal development, parturition, or postnatal development; definitive animal studies have not been completed yet. The full relevance of animal studies to human risk with vaccines for covid-19 remains to be established.

Administration of COVISHIELD in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and the fetus.

Breastfeeding

It is unknown whether the COVISHIELD is excreted in human milk.

Effects on ability to drive and use of machines

ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant) has no or negligible influence on the ability to drive or operate machinery. However some of the adverse effects may temporarily affect the ability to drive or use machinery.
Undesirable effects.

The overall safety of the Covid-19 vaccine AstraZeneca [ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant)] is based on the interim analysis of pooled data from four clinical trials conducted in the United Kingdom, Brazil and South Africa.

At the time of analysis, 23,745 participants aged more than 18 years old have been randomized and given either COVID-19 vaccine AstraZeneca or control. Out of these, 12,021 received at least one dose of the vaccine. The median duration of follow up of the participants was 105 days post dose 1 and 62 days post dose 2.

Demographic characteristics of the participants were generally similar among those who received the covid-10 AstraZeneca vaccine and those who received the control. Overall among the participants who received the AstraZeneca vaccine were aged between 18 to 64 years and 9.7% were aged 65 years or older. The majority of the recipient were whites (75.5%), 10.1% black and 3.5% Asians; 55.8% were female and 44.2% were male.

The most frequently reported adverse reactions were injection site tenderness in more than 60% individuals; injection site pain, headache, fatigue in more than 50% participants; myalgia, malaise in more than 40% cases, pyrexia, chills in more than 30% of the individuals; and athralgia, nausea in more than 20 % of the individuals.

The majority of the adverse reactions were mild to moderate in severity and often resolved in a few days of vaccination. By day 7 the incidence of subjects with at least one local or systemic adverse reactions was 4% and 13% respectively. When compared with the first dose, adverse effects reported after the second dose were milder and reported less frequently.

Adverse reactions were generally milder and reported less frequently in participants who were more than 65 years old.

If required, analgesic and or antipyretic products eg paracetamol containing products my be used

to provide symptomatic relief from the post-vaccination adverse reactions.

Adverse drugs reactions.

Adverse drug reactions are organized by MeDRA System Organ Class (SOC), with each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness. Frequencies occurrence adverse reactions are defined as very common (<1/10); common (>1/100); uncommon (>1000 to <100); rare (>1/10,000 to <1/1000); very rare (<10,000).

Common adverse drug reactions associated with the vaccine are

1. Headache very common
2. Vomiting common
3. Injection site induration common
4. Influenza like illness common
5. Lymphadenopathy
6. Myalgia
7. arthralgia
8. Injection site tenderness
9. Injection site pain
10. Injection site warmth
11. Injection site erythema, pruritus, swelling, bruising,
12. Fatigue
13. Malaise
14. Pyrexia and chills

Effects that occur less commonly are:

1. Decreased appetite
2. Dizziness
3. Abdominal pains
4. Hyperhyroisia
5. Rash
6. Pruritus
7. Headache

Very rare events of neuroinflammatory disorders have been reported following vaccination with covid-19 vaccine AstraZeneca.

Safety profile of COVISHIELD

COVISHIELD was safe and well tolerated in clinical trial phase II/III. an interim analysis included data of all the 1600 participants who received the first dose.