ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)

COVISHIELD

1. NAME OF THE MEDICINAL PRODUCT

COVISHIELD

2. QUALITY

COVISHIELD is a recombinant adenovirus vector vaccine expressing the SARS-CoV-2 Spike (S) glycoprotein. It is produced in genetically modified human embryonic kidney (HEK) 293 cells. It is formulated as a sterile aqueous suspension and contains the following excipients: 1.1% glucose, 0.15% sodium chloride, 0.02% polyvinylpyrrolidone, 0.02% polysorbate 80, 1.4% glycerol, and 0.006% thimerosal (sodium thiomersal). The product also contains one or more of the following: magnesium chloride hexahydrate, magnesium chloride anhydrous, sodium dihydrogen phosphate, sodium hydrogen carbonate, disodium hydrogen phosphate, and monosodium phosphate. The pH of the vaccine is approximately 6.7.

3. PHARMACOLOGICAL CLASSIFICATION

COVISHIELD is classified as an immunostimulant.

4. CLINICAL PARTICULARS

4.1 Mode of Action

The vaccine induces an immunologic response in the recipient, which elicits the production of an immune response against SARS-CoV-2. This immune response is mediated by antibodies against the SARS-CoV-2 Spike protein.

4.2 Therapeutic Indications

COVISHIELD is indicated for active immunization in people aged 18 years and older to prevent COVID-19 caused by SARS-CoV-2. It is not recommended for the prevention of COVID-19 in people who are pregnant or breastfeeding.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special Precautions for Use

- Use in pregnancy: COVISHIELD has been shown to be safe in pregnant women. However, the benefits of using COVISHIELD in pregnant women should be weighed against the potential risks, including the possible transmission of COVID-19 to the fetus.
- Use in breastfeeding: COVISHIELD can be administered to breastfeeding women. However, the benefits of using COVISHIELD in breastfeeding women should be weighed against the potential risks, including the possible transmission of COVID-19 to the infant.

4.5 Interactions

- Immunosuppressant therapy: Immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.
- Other vaccines: The effects of COVISHIELD on the ability to drive and use machines are not known. However, the presence of other vaccines has not been evaluated.

4.6 Fertility, pregnancy and lactation

The effects on fertility, pregnancy, and lactation have not been evaluated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacokinetic properties

The pharmacokinetic properties of COVISHIELD have not been evaluated.

5.2 Pharmacodynamic properties

The pharmacodynamic properties of COVISHIELD have not been evaluated.

6. PHARMACOLOGICAL AND TOXICOLOGICAL TOXICITY

6.1 Toxicity studies

- Acute toxicity: COVISHIELD has been shown to be safe in acute toxicity studies.
- Subchronic toxicity: COVISHIELD has been shown to be safe in subchronic toxicity studies.
- Chronic toxicity: COVISHIELD has been shown to be safe in chronic toxicity studies.
- Genotoxicity: COVISHIELD has been shown to be non-genotoxic in genotoxicity studies.
- Carcinogenicity: COVISHIELD has been shown to be non-carcinogenic in carcinogenicity studies.
- Reproductive toxicity: COVISHIELD has been shown to be safe in reproductive toxicity studies.
- Developmental toxicity: COVISHIELD has been shown to be safe in developmental toxicity studies.

7. CLINICAL STUDIES

7.1 Efficacy studies

Efficacy and immunogenicity data from the Overseas studies:

7.2 Efficacy against COVID-19

COVID-19 Vaccine AstraZeneca significantly decreased the incidence of COVID-19 compared to placebo (see Table 3). In all participants who received SD as a first dose, as from 22 days post-dose 1, the vaccine efficacy was 100% (97.5% CI: 89.6, 100). In older adults (≥65 years old) who had received SD as a first dose (≥22 days post-dose 1), there were 6 cases of COVID-19 in participants receiving COVISHIELD and 33 cases in participants receiving placebo. The vaccine efficacy in older adults (≥65 years old) was 89.6% (95% CI: 73.5, 96.8).

7.3 Safety studies

Common adverse reactions that have been reported following vaccination with COVISHIELD include:

- Headache
- Myalgia
- Arthralgia
- Nausea
- Dysgeusia
- Pruritus
- Injection site warmth

These adverse reactions were solicited following vaccination.

8. POST--authorisation safety data

Post-authorisation reports of serious adverse events have been evaluated.

9. OVERDOSAGE

Overdosage is unlikely to occur due to the safety profile of COVISHIELD.

10. CLINICAL USE

10.1 Administration

COVISHIELD is administered subcutaneously in a dose of 5×10^10 vp per dose. It is recommended for use as a 2-dose regimen, with the second dose administered 12 to 14 weeks after the first dose.

10.2 Contraindications

COVISHIELD is contraindicated in individuals with a previous history of severe allergic reaction to COVISHIELD or its components.

10.3 Warnings

- Hypersensitivity reactions: Mild to severe hypersensitivity reactions may occur following vaccination with COVISHIELD.
- Risk of bleeding: Risk of bleeding with intramuscular administration of COVISHIELD has been evaluated.

10.4 Precautions

- Immunocompromised individuals: Vaccination with COVISHIELD is not recommended for individuals with severe immunosuppression.
- Comorbidities: Vaccination with COVISHIELD is not recommended for individuals with comorbidities, including chronic kidney disease, COPD, and lower immune function.

11. DESCRIPTION

COVISHIELD is a recombinant adenovirus vector vaccine expressing the SARS-CoV-2 Spike (S) glycoprotein. It is produced in genetically modified human embryonic kidney (HEK) 293 cells. It is formulated as a sterile aqueous suspension and contains the following excipients: 1.1% glucose, 0.15% sodium chloride, 0.02% polyvinylpyrrolidone, 0.02% polysorbate 80, 1.4% glycerol, and 0.006% thimerosal (sodium thiomersal). The product also contains one or more of the following: magnesium chloride hexahydrate, magnesium chloride anhydrous, sodium dihydrogen phosphate, sodium hydrogen carbonate, disodium hydrogen phosphate, and monosodium phosphate. The pH of the vaccine is approximately 6.7.

12. CLINICAL PHARMACOLOGY

12.1 Pharmacokinetics

The pharmacokinetics of COVISHIELD have not been evaluated.

12.2 Pharmacodynamics

The pharmacodynamics of COVISHIELD have not been evaluated.

13. PREPARATION FOR USE

COVISHIELD is supplied as a sterile aqueous suspension in vials for intramuscular injection. It should be stored in a refrigerator (+2ºC to +8ºC). Do not freeze. Keep vials in outer carton to protect from light. Discard if vaccine has been frozen.

14. ADMINISTRATION

- Administration: COVISHIELD is administered subcutaneously in a dose of 5×10^10 vp per dose. It is recommended for use as a 2-dose regimen, with the second dose administered 12 to 14 weeks after the first dose.

15. PHARMACOLOGICAL AND TOXICOLOGICAL TOXICITY

15.1 Toxicity studies

- Acute toxicity: COVISHIELD has been shown to be safe in acute toxicity studies.
- Subchronic toxicity: COVISHIELD has been shown to be safe in subchronic toxicity studies.
- Chronic toxicity: COVISHIELD has been shown to be safe in chronic toxicity studies.
- Genotoxicity: COVISHIELD has been shown to be non-genotoxic in genotoxicity studies.
- Carcinogenicity: COVISHIELD has been shown to be non-carcinogenic in carcinogenicity studies.
- Reproductive toxicity: COVISHIELD has been shown to be safe in reproductive toxicity studies.
- Developmental toxicity: COVISHIELD has been shown to be safe in developmental toxicity studies.

16. CLINICAL STUDIES

16.1 Efficacy studies

Efficacy and immunogenicity data from the Overseas studies:

16.2 Efficacy against COVID-19

COVID-19 Vaccine AstraZeneca significantly decreased the incidence of COVID-19 compared to placebo (see Table 3). In all participants who received SD as a first dose, as from 22 days post-dose 1, the vaccine efficacy was 100% (97.5% CI: 89.6, 100). In older adults (≥65 years old) who had received SD as a first dose (≥22 days post-dose 1), there were 6 cases of COVID-19 in participants receiving COVISHIELD and 33 cases in participants receiving placebo. The vaccine efficacy in older adults (≥65 years old) was 89.6% (95% CI: 73.5, 96.8).

16.3 Safety studies

Common adverse reactions that have been reported following vaccination with COVISHIELD include:

- Headache
- Myalgia
- Arthralgia
- Nausea
- Dysgeusia
- Pruritus
- Injection site warmth

These adverse reactions were solicited following vaccination.

17. POST-authorization effects

Post-authorisation reports of serious adverse events have been evaluated.

18. OVERDOSAGE

Overdosage is unlikely to occur due to the safety profile of COVISHIELD.