### 4.8 Adverse reactions

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Total cases</th>
<th>Total (%)</th>
<th>Control</th>
<th>Total cases</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Vaccine AstraZeneca</td>
<td>1374 (15.23)</td>
<td>1.59</td>
<td>0.005</td>
<td>2 (0.02)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

#### Caution

- **Contraindications:**
  - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- **Precautions for use:**
  - Elderly population
  - Special populations
  - Breastfeeding

- **Use in pregnancy:**
  - It is unknown whether COVISHIELD™ is excreted in human milk. Breastfeeding is not recommended.

- **Effects on ability to drive and use machines:
  - The vaccine may temporarily affect the ability to drive or use machines.

- **Drug interactions:**
  - None known.

### 5.1 Immunogenicity

- The majority of participants across the study arms achieved immune responses similar to those observed in the overseas studies (see section 5.1).
- The safety and efficacy of COVISHIELD™ is indicated for active immunisation of individuals ≥18 years old for the prevention of coronavirus disease (COVID-19) caused by SARS-CoV-2.

### 5.2 Duration and level of protection

- For the primary end point, vaccine efficacy was evaluated in participants who completed the vaccination course with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.
- For the secondary end point, vaccine efficacy was evaluated in participants who completed the vaccination course with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.

### 5.3 Exploratory analysis

- Primary analysis population: 2,070 (35.6%) participants had at least one pre-existing comorbidity (defined as a BMI ≥ 30 kg/m², cardiovascular disease, diabetes, or chronic obstructive pulmonary disease).
- Secondary analysis population: 2,070 (35.6%) participants had at least one pre-existing comorbidity (defined as a BMI ≥ 30 kg/m², cardiovascular disease, diabetes, or chronic obstructive pulmonary disease).

### 5.4 Primary results

- For the primary end point, vaccine efficacy was 79.4% (95% CI: 70.5; 84.8) in the 525,284.8 participants who completed the vaccination course with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.
- For the secondary end point, vaccine efficacy was 86.8% (95% CI: 78.6; 91.2) in the 525,284.8 participants who completed the vaccination course with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.

### 5.5 Additional exploratory analyses

- Of the 2,070 participants with at least one pre-existing comorbidity, 42 (1.99%) had a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.
- Of the 2,070 participants with at least one pre-existing comorbidity, 42 (1.99%) had a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course.

### 5.6 Additional analyses for the secondary end point

- In all participants, vaccine efficacy was 79.4% (95% CI: 70.5; 84.8).
- In participants with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course, vaccine efficacy was 86.8% (95% CI: 78.6; 91.2).

### 5.7 Additional analyses for the primary end point

- In all participants, vaccine efficacy was 79.4% (95% CI: 70.5; 84.8).
- In participants with a confirmed infection of COVID-19 disease within 12 months of completing the vaccination course, vaccine efficacy was 86.8% (95% CI: 78.6; 91.2).
Vaccine name: ChAdOx1 nCoV-

This vaccine is an adenovirus-based vaccine. It uses a modified virus that does not cause disease in humans to deliver the SARS-CoV-2 virus spike protein, which the immune system then recognizes and builds a response against.

The vaccine is given as a single dose. It is not recommended for use in children under the age of 12 years.

The vaccine is stable at room temperature for up to 12 months and can be stored at 2-8°C for up to 3 months. It can also be stored at -20°C and -80°C for longer periods.

The vaccine is given as a single dose and is administered intramuscularly. It is not recommended for use in immunocompromised individuals.

The vaccine is not recommended for use in pregnant women. However, if a pregnant woman receives the vaccine, she should be advised to use a contraceptive method during the first trimester of pregnancy.

The vaccine is not recommended for use in breastfeeding women. However, if a breastfeeding woman receives the vaccine, she should be advised to check with her healthcare provider about the potential risks and benefits of breastfeeding.

No serious side effects have been reported with this vaccine. The most common side effects include:

- Mild fever
- Soreness at the injection site
- Fatigue
- Headache
- Myalgia

These side effects usually resolve on their own within a few days. If you develop any severe or persistent side effects, you should seek medical attention.

It is important to note that this vaccine is only effective if it is given on time. If you miss a dose, you should get it as soon as possible. However, if it has been more than 28 days since your previous dose, you should start the vaccination series again.

It is also important to note that this vaccine is not a cure for COVID-19. It is designed to help your body build immunity against the virus, which can reduce the severity of the disease if you do contract it.

Remember, vaccination is important to protect yourself and others from COVID-19. Please talk to your healthcare provider about the benefits and risks of this vaccine and other vaccination options available to you.