COVID-19 Vaccine* Product Information model
November 2020

*For non-replicating viral vector COVID-19 vaccines

1. NAME OF THE MEDICINAL PRODUCT

[NAME (SHORT NAME)]
[e.g.] COVID-19 vaccine (vector e.g. ChAdOx1-S / Ad26-S, recombinant)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose ([X] mL) contains:

Virus XX encoding the SARS CoV-2 (antigen-Spike protein)∗, not less than XXX infectious units (Inf.U)∗

*produced in XX cells and by recombinant DNA technology

This product contains genetically modified organisms (GMOs).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

[Pharmaceutical form, e.g., Suspension for injection]

[Colour and aspect – E.g. Colourless to slightly yellow, clear to very opalescent suspension].

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[NAME or SHORT NAME] is indicated for active immunisation for prevention of COVID-19 caused by SARS-CoV-2 in individuals above [AGE] [see sections 4.4 and 5.1].

The use of the vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

[NAME or SHORT NAME] should be administered by a trained healthcare professional
Primary vaccination
A dose ([X] mL) of [NAME or SHORT NAME] should be administered [as the first vaccination].

[Whenever appropriate] A dose ([X] mL) of [NAME or SHORT NAME] should be administered as the second vaccination approximately [X] days/weeks after the first vaccination with [NAME or SHORT NAME].

[Whenever appropriate (If a booster vaccination is recommended)] Booster vaccination with [NAME or SHORT NAME]
Individuals who have previously completed the 2-dose primary vaccination regimen can receive a booster dose of [NAME or SHORT NAME]. [Timing of the booster dose should be included]

Corrective measures in case of inadvertent administration [Whenever appropriate. E.g. when two vaccines have to be administered in a specific order]


Paediatric population
[Whenever appropriate] No data are available on the safety and efficacy of the vaccination regimen in children and adolescents aged <18 years.

Elderly population
[If applicable]
The safety profile of [NAME or SHORT NAME] in the elderly [>60 or >65 years of age] was generally similar to that observed in adults.

Dosage adjustment
[Keep only if there is need to have a specific posology. E.g. elderly population]

Method of administration

Intramuscular (IM) use. The preferred site is the deltoid muscle of the upper arm.

Do not administer this vaccine intravenously or subcutaneously.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For precautions regarding thawing, handling and disposal of the vaccine, see section 6.6.
4.3 Contraindications

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

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity

Close observation is recommended following vaccination for the early signs of anaphylaxis or anaphylactoid reactions. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylactic reactions following the administration of the vaccine. Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Thrombocytopenia and coagulation disorders

The vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding or bruising may occur following an intramuscular administration in these individuals.

Concurrent illness

Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection, unless the benefit of immediate vaccination outweighs the potential risks. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Immunocompromised individuals

Safety and immunogenicity of [NAME or SHORT NAME] has not been assessed in immunocompromised individuals, including those receiving immunosuppressive therapy. Immunocompromised individuals may not respond as well as immunocompetent individuals to vaccination with [NAME or SHORT NAME].

Duration of protection

The duration of protection afforded by [NAME or SHORT NAME] is unknown as it is still being determined by ongoing clinical trials. [Update text once the results become available]
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Protection against disease caused by other coronaviruses

Vaccination with [NAME or SHORT NAME] is not intended to prevent diseases caused by other coronaviruses such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).

4.5 Interaction with other medicinal products and other forms of interaction

The safety, immunogenicity and efficacy of co-administration of [NAME or SHORT NAME] with other vaccines have not been evaluated, and therefore, co-administration is not recommended.

If [NAME or SHORT NAME] must be given at the same time as another injectable vaccine(s), then the vaccine(s) should always be administered at different injection sites. Do not mix [NAME or SHORT NAME] with any other vaccine in the same syringe or vial.

4.6 Fertility, pregnancy and lactation

Pregnancy

[Text may be changed based on actual data available at the time of approval]

There are no data from the use of [NAME or SHORT NAME] in pregnant women.

Animal studies to assess direct or indirect harmful effects of [NAME or SHORT NAME] with respect to reproductive toxicity are ongoing. [Update text once the results become available]

As a precautionary measure, it is preferable to avoid vaccination with [NAME or SHORT NAME] during pregnancy.

Breast-feeding

It is not known whether [NAME or SHORT NAME] is excreted in human milk. A risk to the newborns/infants from breast-feeding by vaccinated mothers cannot be excluded. As a precautionary measure, it is preferable to avoid vaccination with [NAME or SHORT NAME] during breast-feeding.

Fertility

[Text may be changed based on actual data available at the time of approval]

Animal studies to assess direct or indirect harmful effects of [NAME or SHORT NAME] with respect to reproductive toxicity are ongoing. [Update text once the results become available]

4.7 Effects on ability to drive and use machines

[NAME or SHORT NAME] has no known effect on the ability to drive and use machines.
4.8 Undesirable effects

Summary of the safety profile

The most common local adverse reactions reported in adults who received [NAME or SHORT NAME] were [list the most common, followed by the percentage, in parentheses. E.g., pain ([X]%), warmth ([X]%) and swelling ([X]%) at the injection site]. The most common systemic adverse reactions were [list the most common, followed by the percentage, in parentheses. E.g., fatigue ([X]%), headache ([X]%) and myalgia ([X]%). Most adverse reactions occurred within [X] days following vaccination and were [mild, moderate or severe] and of [short, long] duration ([X] days).

The most common local adverse reactions reported in the elderly [>60 or >65 years of age] who received [NAME or SHORT NAME] were [list the most common, followed by the percentage, in parentheses. E.g., pain ([X]%), warmth ([X]%) and swelling ([X]%) at the injection site]. The most common systemic adverse reactions were [list the three most common, followed by the percentage, in parenthesis. E.g., fatigue ([X]%), headache ([X]%) and myalgia ([X]%). Most adverse reactions occurred within [X] days following vaccination and were [mild, moderate or severe] and of [short, long] duration ([X] days).

Tabulated list of adverse reactions

Adverse reactions observed during clinical studies are listed below by the following frequency categories:
very common (≥1/10);
common (≥1/100 to <1/10);
uncommon (≥1/1000 to <1/100);
rare (≥1/10000 to <1/1000).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Adults
Table 1 shows the adverse reactions reported from clinical trials in adults.

Table 1: Adverse Reactions Reported in Adults Following Vaccination with [NAME or SHORT NAME]

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Frequency</th>
<th>Adverse reactions</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders</td>
<td>very common</td>
<td>headache</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>uncommon</td>
<td>dizziness postural</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>common</td>
<td>vomiting</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>very common</td>
<td>arthralgia, myalgia</td>
<td></td>
</tr>
<tr>
<td>General disorders and</td>
<td>very common</td>
<td>pruritus</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>chills, fatigue, injection site</td>
<td></td>
</tr>
</tbody>
</table>
administration site conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>pain, injection site swelling, injection site warmth</td>
<td>common</td>
</tr>
<tr>
<td>pyrexia, injection site pruritus</td>
<td>uncommon</td>
</tr>
<tr>
<td>injection site induration, injection site erythema</td>
<td>uncommon</td>
</tr>
</tbody>
</table>

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**Elderly**

Table 2 shows the adverse reactions reported from clinical trials in the elderly [only relevant if different from adults].

Table 2: Adverse Reactions Reported in the Elderly Following Vaccination with [NAME or SHORT NAME] (as example in Table 1)

**Description of selected adverse reactions**

Add text as relevant

**Paediatric population**

Add text as relevant

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

**4.9 Overdose**

No case of overdose has been reported.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Vaccine, other viral vaccines, ATC code: J07BX... [Fill in correct code]

**Mechanism of action**

[NAME or SHORT NAME] [Fill in information]

**Efficacy**

[Summarize result(s) of efficacy studies from placebo controlled randomised clinical trial(s), with a short description of the study design, providing estimates of vaccine efficacy for the studied outcomes (e.g. COVID-19, hospitalisation) and 95% confidence intervals]. State
numbers of participants. Present the results stratified by adults and elderly, and, whenever possible, by other covariates.

**Immunogenicity**

[Summarize result(s) of immunogenicity studies from relevant clinical trial(s), stating number of participants, and the relevant results. E.g. Geometric Mean Titres (GMT) of neutralizing antibodies against SARS-CoV-2 measured X days after immunization; Add information on correlate(s) of protection]

*Long term immunogenicity*
[Provide the information available]

**Paediatric population**
[Add text as relevant, including standard info on Paediatric Investigation Plan (PIP) and deferral of studies]

**5.2 Pharmacokinetic properties**

Not applicable.

**5.3 Preclinical safety data**

Non-clinical data revealed no special hazard for humans based on [state types of studies conducted, in which animal(s). A reproductive toxicity study in [animal] is ongoing.]

[GMO information the context of the Environment Risk Assessment (ERA), if relevant]

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

[List all excipients]

**6.2 Incompatibilities**

In the absence of compatibility studies, [NAME or SHORT NAME] must not be mixed with other medicinal products.

**6.3 Shelf life**

[Time in months/years] at -60°C to -80°C, -25°C to -15°C and +2°C to +8°C. Product specific. Temperature range to be included in this section only if different shelf life applies]

**6.4 Special precautions for storage**

Transport [State required conditions, e.g. frozen at -25°C to -15°C storage temperature requirement. Upon receipt, the vaccine can be stored as indicated below:}
Store [State required conditions. Important to distinguish the need for freezer -20°C or below or refrigerator 2-8°C, stating the temperature ranges]

Once thawed, the vaccine cannot be refrozen.

The vial must be kept in the original package in order to protect from light and to track the expiry or discard date for the different storage conditions.
[This may not always be the case for very large pack sizes and if the company has shown no photostability issues. To be decided during EUL]

6.5 Nature and contents of container

[Description, e.g. 0.5 mL suspension in a (single/ multi dose) Type I glass vial with a rubber stopper (chlorobutyl with fluoropolymer coated surface), aluminium crimp and red plastic cap.] 
[This material is not standard for all products, might be different type of stopper, cap etc]

For multidose: The volume of 1 vial after adding X mL diluent corresponds to Y doses of vaccine (Z mL)]

Pack size of [number of vials].

6.6 Special precautions for disposal and other handling

[Provide relevant information]

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER/ EMERGENCY USE APPROVAL HOLDER or EQUIVALENT

[Name and address of manufacturer]

8. MARKETING AUTHORISATION NUMBER(S) /EMERGENCY USE APPROVAL OR EQUIVALENT

09. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT