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COVID-19 Vaccine Janssen® (active substance: human adenovirus serotype 26* encoding the SARS-CoV-2 spike glycoprotein (Ad26.Cov2-S)

Temporary authorisation in Switzerland: 22 March 2021

Medicinal product (vaccine) for the prevention of COVID-19 in adults

About the medicinal product

The medicinal product (vaccine) COVID-19 Vaccine Janssen, containing the active substance human adenovirus serotype 26* encoding the SARS-CoV-2 spike glycoprotein (Ad26.Cov2-S), is a ready-to-use suspension for injection[1].

The vaccine is designed to prevent COVID-19, which is caused by the SARS-CoV-2 virus (coronavirus).

SARS-CoV-2 is a new coronavirus that was discovered in China at the end of 2019. Owing to the rapid increase in case numbers in many countries and continents, the WHO (World Health Organization) officially declared the outbreak to be a pandemic on 11 March 2020.

By the start of December 2021, in Switzerland over 1,000,000 people had contracted COVID-19, over 35,000 had been admitted to hospital and over 11,000 had died from the consequences of COVID-19 (Covid-19 Switzerland | Coronavirus | Dashboard (admin.ch))

COVID-19 Vaccine Janssen was authorised by Swissmedic on 22 March 2021 for use in adults.

Mode of action

COVID-19 Vaccine Janssen causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, thereby affording protection against COVID-19.

For a detailed explanation of the mode of action of vaccines, we recommend the video "How a vector vaccine works" or the Swissmedic videos on the vaccines generally.

[1] Suspension for injection: liquid dosage form that is administered with a syringe

Use

COVID-19 Vaccine Janssen is administered by a correspondingly trained healthcare professional in accordance with the current vaccination strategy.

COVID-19 Vaccine Janssen is injected into a muscle, usually in the upper arm. One 0.5 ml dose of COVID-19 Vaccine Janssen is administered for the basic immunisation.

Efficacy

The efficacy of COVID-19 Vaccine Janssen in adults was compared with placebo (dummy drug) in the study COV3001 with over 40,000 participants.

Healthy volunteers and study participants with stable chronic illnesses each received one dose of COVID-19 Vaccine Janssen or placebo.

The median[2] follow-up period after vaccination until the final efficacy analyses was 2 months. The reliability of COVID-19 Vaccine Janssen in preventing COVID-19 was investigated.

In the event of exposure to the virus, those individuals who were vaccinated with COVID-19 Vaccine Janssen were 66.9% (or 66.1%, respectively) less likely to suffer from moderate to severe/critical COVID-19 at least 14 days (or at least 28 days, respectively) after vaccination than those who received a placebo vaccine.

Furthermore, the probability of contracting severe/critical COVID-19 at least 14 days (or at least 28 days, respectively) after vaccination with COVID-19 Vaccine Janssen was 76.7% (or 85.4%, respectively) lower than after treatment with placebo.

Precautions, undesirable effects & risks

COVID-19 Vaccine Janssen must not be used in those who are hypersensitive to the active substance or any of the excipients.

Like all vaccines, COVID-19 Vaccine Janssen can also produce side effects, although not necessarily in everyone. The most common adverse reactions are headache, nausea, muscle pain, injection site pain, chills, joint pain, cough and fever.
Very rare cases of anaphylaxis (acute, allergic reactions) have also been reported after vaccination with COVID-19 Vaccine Janssen. Therefore, monitoring of patients for at least 15 minutes for hypersensitivity reactions and anaphylaxis is recommended following vaccination.

All precautions, risks and other possible undesirable effects are listed in the Information for patients and the Information for healthcare professionals. (see link at the end of this document).

Why the medicinal product has been authorised

The medicinal product COVID-19 Vaccine Janssen was the third COVID-19 vaccine to receive temporary authorisation in Switzerland.

[2] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

The submitted data show that a single dose of the active substance is effective, after at least 14 days, in preventing moderate to severe/critical COVID-19.

This means that, out of 100 people exposed to the virus who would have contracted COVID-19 without vaccination, only 33 vaccinated individuals actually suffer a moderate to severe/critical case of the illness. However, it does not mean that the probability of contracting moderate to severe/critical COVID-19 after vaccination is 33%. The infection risk depends on the vaccination status (high protection against infection following exposure to the virus) but also on the frequency of the illness in the population, the precautions taken and individual behaviour. These factors determine the magnitude of the risk of coming into contact with the virus.

Given the exceptional situation of the pandemic, taking account of all the risks and precautions, and on the basis of the available data, the benefit of COVID-19 Vaccine Janssen in reducing the risk of COVID-19 infection clearly outweighs its potential safety risks.

The medicinal product COVID-19 Vaccine Janssen was authorised in Switzerland on a temporary basis (in accordance with Art. 9a of the Therapeutic Products Act) since the clinical trials had not yet been concluded at the time of authorisation, and further data for the definitive evaluation of efficacy and safety will be submitted at a later date.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic from ongoing clinical trials. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation.

COVID-19 Vaccine Janssen was also authorised according to the "rolling submission" procedure. Rolling submission is a special form of authorisation for new active substances that has been adopted in the pandemic situation and is intended to facilitate faster authorisation of urgently needed medicinal products. Using this procedure, Swissmedic can review data from ongoing clinical trials as soon as they become available.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals COVID-19 Vaccine Janssen®

Information for patients (package leaflet): Patient information COVID-19 Vaccine Janssen®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.