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Public Summary SwissPAR dated 10 February 2023

Nuvaxovid® (active substance: SARS CoV-2 recombinant spike protein (rS NVX-CoV2373))

Temporary indication extension in Switzerland: 2 September 2022

Medicinal product (vaccine) for the prevention of COVID-19 in adults and adolescents aged 12 years and older

Information on authorisation

Nuvaxovid was authorised for the prevention of COVID-19 in adults on 12 April 2022. This indication extension means that adolescents aged 12 years and over can now also be vaccinated.

Nuvaxovid, containing the active substance SARS-CoV-2 recombinant spike protein, is used to prevent COVID-19, which is caused by the SARS-CoV-2 virus.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialist white blood cells that fight the virus, thereby protecting against COVID-19. For more detailed explanations of the mode of action of protein vaccines, we recommend the Swissmedic videos on vaccines.

In deciding whether to extend the indication of the medicinal product Nuvaxovid, Swissmedic took into account the assessment of the European Medicines Agency (EMA) regarding certain aspects such as the clinical data, as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment report of a foreign authority, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign reference authority.

(www.ema.europa.eu)

The indication extension for the medicinal product Nuvaxovid has been authorised temporarily in Switzerland (in accordance with Art. 9a of the Therapeutic Products Act) since not all results of clinical trials were available or not all clinical trials had been concluded at the time of authorisation.
The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Nuvaxovid

Information for patients (package leaflet): Patient information Nuvaxovid

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.