swissmedic

Public Summary SwissPAR dated 7 July 2022

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

Temporary authorisation in Switzerland: 12 April 2022

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

Information on authorisation

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. Nuvaxovid is administered to adults aged 18 years and over.

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 a more detailed explanation of the mode of action of protein vaccines, we recommend the Swissmedic videos on vaccines.

Nuvaxovid was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by the foreign regulatory agency, provided certain requirements are fulfilled. These involve checks on the quality, efficacy and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Nuvaxovid in Switzerland, Swissmedic accepted parts of the assessment and approval decision of the European authority (EMA) and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report and the short report issued by the reference authority: (www.ema.europa.eu)

The medicinal product Nuvaxovid has been authorised temporarily in Switzerland (in accordance with Art. 9a TPA) 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.