swissmedic

Summary report on authorisation dated 19 August 2025

mRESVIA® (active substance: Respiratory syncytial virus (RSV) mRNA vaccine (nucleoside-modified))

Authorisation in Switzerland: 17 April 2025

Dispersion for injection in a pre-filled syringe for the prevention of respiratory tract disease caused by the respiratory syncytial virus (RSV) in adults 60 years of age and older

About the medicinal product

mRESVIA is a vaccine that helps to protect adults aged 60 years and older against infection with respiratory syncytial virus (RSV).

RSV is a highly contagious virus that can cause respiratory tract disease. Older people are at higher risk of serious complications.

mRESVIA contains a special messenger RNA (mRNA) that stimulates the body to recognise a specific protein of the RSV and form antibodies against it, thereby enabling the immune system to attack the virus during a subsequent contact and protect the individual from lower respiratory tract illnesses.

mRESVIA 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 foreign regulatory agencies, 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 mRESVIA in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; EMA/285703/2024) and has only conducted a limited scientific review.

Since the assessment was based on the assessment report of the foreign partner authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign comparator product www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals mResvia®

Information for patients (package leaflet): Information for patients mResvia®

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 Summary report on authorisation.

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.