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Public Summary SwissPAR dated 17 August 2022

Fluenz Tetra® (active substance: live, attenuated influenza virus from the strains *A (H1N1), A (H3N2), B (Yamagata)* and *B (Victoria)*)

First authorisation in Switzerland: 11 May 2022

Medicinal product (vaccine) for the prevention of influenza (flu) in children and adolescents aged between 24 months and 18 years.

About the medicine

The medicinal product Fluenz Tetra contains the live, attenuated[1] influenza virus of the strains *(H1N1), A (H3N2), B (Yamagata) and B (Victoria)* as the active substance. It is a nasal spray for single use and is used in children and adolescents aged between 24 months and 18 years. Children aged 2–8 years who have not been vaccinated against flu before should receive a second dose.

Fluenz Tetra is a vaccine used for the prevention of influenza (flu) caused by the two influenza A virus types and the two influenza B virus types included in the vaccine.

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

Flu is a disease of the respiratory tract that is caused by influenza viruses and infects the nose, throat and lungs. Small children, the elderly and especially vulnerable individuals are at increased risk of suffering from a serious complication of flu such as severe pneumonia and secondary bacterial infections.

Each year, seasonal flu leads to between 112,000 and more than 250,000 visits to the doctor in Switzerland. As a result of possible complications, flu is responsible for thousands of hospital stays and several hundred deaths a year.

Flu vaccination is the most important public healthcare measure for reducing the annual burden associated with flu epidemics.

The WHO recommends the composition of the seasonal flu vaccine for the northern hemisphere in the first quarter of a given calendar year based on the circulating viruses.

[1] Live, attenuated: A live vaccine contains pathogens that are capable of reproduction (live) but weakened (attenuated).

In deciding whether to authorise the medicinal product Fluenz Tetra, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) 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 reports of the foreign partner authorities, 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 comparator products.

www.ema.europa.eu
www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Fluenz Tetra®

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.