Fluenz Tetra®

0.2 ml, Nasal spray, suspension in a single-use nasal applicator

Summary of the Risk Management Plan (RMP) for Fluenz Tetra® Reassortant influenza virus strains (live attenuated) of types A/H1N1, A/H3N2, B/Yamagata and B/Victoria

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Disclaimer:
The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them. The RMP summary of Fluenz Tetra® is a concise document and does not claim to be exhaustive.
As the RMP is an european document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Fluenz Tetra® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. "AstraZeneca AG" is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fluenz Tetra®.

VI: 1 THE MEDICINE AND WHAT IT IS USED FOR

FLUENZ TETRA is authorised for Prophylaxis of influenza in children from 24 months to less than 18 years of age. It contains Influenza vaccine (live attenuated, nasal) as the active substance and it is given by nasal route of administration, one 0.2-mL dose (administered as 0.1 mL per nostril).

VI: 2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Fluenz Tetra, together with measures to minimise such risks and the proposed studies for learning more about Fluenz Tetra's risks, are outlined below.
Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and PI addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.
In addition to these measures, information about adverse reactions is collected continuously and regularly analysed including PBRER assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

VI: 2.1 LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Fluenz Tetra are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Fluenz Tetra. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

There are no important risks or missing information for LAIV.

VI: 2.2 Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

VI: 2.3 Post-authorisation development plan

VI: 2.3.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligations for Fluenz Tetra.

VI: 2.3.2 Other studies in post-authorisation development plan

There are no studies required for Fluenz Tetra®.