

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR

This is a summary of the risk management plan (RMP) for Fluenz Tetra. The RMP details important risks of Fluenz Tetra, how these risks can be minimised, and how more information will be obtained about Fluenz Tetra's risks and uncertainties (missing information).

Fluenz Tetra's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fluenz Tetra should be used.

This summary of the RMP for Fluenz Tetra should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Fluenz Tetra's RMP.

1 THE MEDICINE AND WHAT IT IS USED FOR

FLUENZ TETRA is authorised for Prophylaxis of influenza in children and adolescents 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).

Further information about the evaluation of Fluenz Tetra's benefits can be found in Fluenz Tetra's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002617/human_med_001713.jsp&mid=WC0b01ac058001d124

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 SmPC 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 PSUR assessment - so that immediate action can be taken as necessary. These measures constitute routine *pharmacovigilance activities*.

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.

There are no important risks or missing information for Fluenz Tetra.

2.2 Summary of important risks

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

2.3 Post-authorisation development plan

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.

2.3.2 Other studies in post-authorisation development plan

There are no studies required for Fluenz Tetra.