Part VI: Summary of the risk management plan

Summary of risk management plan for *Oseltamivir*, powder for oral solution in sachet, 75 mg.

This is a summary of the risk management plan (RMP) for *Oseltamivir*, powder for oral solution in sachet, 75 mg. The RMP does not detail any risks and missing information as none were identified. However, it presents routine pharmacovigilance activities for uncertainties (important identified risks, important potential risks, and missing information).

Oseltamivir, powder for oral solution in sachet, 75 mg summary of product characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how *Oseltamivir*, powder for oral solution in sachet, 75 mg should be used.

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I. The medicine and what it is used for

Oseltamivir, powder for oral solution in sachet, 75 mg is indicated in adults and children > 40 kg for the treatment and prevention of influenza for 5 or 10 days (see SmPC). *Oseltamivir*, powder for oral solution in sachet, 75 mg is a pro-drug of the oseltamivir carboxylate which is a potent and selective inhibitor of influenza virus neuraminidase enzyme, which activity is important for viral entry into uninfected cells, for the release of recently formed virus particles from infected cells, and for the further spread of the infectious virus (for more information see SmPC for the full indication). It contains oseltamivir as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Possible future important risks of *Oseltamivir*, powder for oral solution in sachet, 75 mg, together with measures to minimise such risks and the proposed studies for learning more about oseltamivir 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.

II.A List of important risks and missing information

Important risks are risks that need special risk management activities to further investigate or minimize 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 oseltamivir. 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).

Table 2 List of important risks and missing information**.**

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorization or specific obligation of *Oseltamivir*, powder for oral solution in sachet, 75 mg.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for *Oseltamivir*, powder for oral solution in sachet, 75 mg.