Xofluza® (Baloxavir marboxil)
Filmtabletten 20mg & 40mg
Zul.-Nr. 67426
Granulat zur Herstellung einer Suspension zum Einnehmen 2mg/ml
Zul.-Nr. 68068

Public Risk Management Plan (RMP) Summary

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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 Xofluza® is a concise document and does not claim to be exhaustive. As the RMP is an international 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 Xofluza® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Roche Pharma (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Xofluza®.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR XOFLUZA (BALOXAVIR MARBOXIL)

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

Xofluza's prescribing information and its package leaflet give essential information to healthcare professionals and patients on how Xofluza should be used.

This summary of the RMP for Xofluza 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 SwissPAR.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Xofluza is indicated for the treatment of uncomplicated influenza in patients aged 12 years and above who have been symptomatic for no more than 48 hours and who are otherwise healthy, or at high risk of developing influenza-related complications. Xofluza is also indicated for the post-exposure prophylaxis of influenza in individuals aged 12 years and above (see prescribing information for the full indication). It contains baloxavir marboxil as the active substance, and it is given orally.

Further information about the evaluation of Xofluza's benefits can be found in Xofluza's SwissPAR, including in its plain-language summary, available on Swissmedic Website (www.swissmedic.ch).

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Xofluza, together with measures to minimize such risks and the proposed studies for learning more about Xofluza's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and prescribing information addressed to patients and healthcare professionals
- Important advice on the medicine's packaging
- The authorized pack size - the amount of medicine in a pack is chosen so as 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.
In addition to these measures, information about adverse events is collected continuously and regularly analyzed, including periodic safety update report (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 of Xofluza are risks that need special risk-management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 Xofluza. 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 about 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).

List of Important Risks and Missing Information	
Important identified risks	*none*
Important potential risks	*none*
Missing information	*none*

II.B SUMMARY OF IMPORTANT RISKS

There are no important identified risks, important potential risks, or missing information for baloxavir marboxil.

II.C POST-AUTHORIZATION DEVELOPMENT PLAN

II.C.1 Studies That Are Conditions of the Marketing Authorization

There are no studies that are conditions of the marketing authorization or specific obligation of Xofluza.

II.C.2 Other Studies in Post-Authorization Development Plan

There are no studies required for Xofluza.