**Summary of Risk Management Plan for Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten (fexofenadine hydrochloride)**

This is a summary of the risk management plan (RMP) for Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten. The RMP details important risks of fexofenadine, how these risks can be minimised, and how more information will be obtained about fexofenadine's risks and uncertainties (missing information).

Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten's RMP.

## I. The Medicine and What it is Used For

Fexofenadine HCl Viatris 120 mg filmomhulde tabletten is indicated in adults and children 12 years and older for the relief of symptoms associated with seasonal allergic rhinitis and Fexofenadine HCl Viatris 180 mg filmomhulde tabletten is indicated in adults and children 12 years and older for the relief of symptoms associated with chronic idiopathic urticaria. It contains fexofenadine hydrochloride as the active substance, and it is given by oral route of administration.

## II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment (include PSUR statement only if product has PSUR requirements, as per EURD list), 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 Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten. 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/use in special patient populations etc.);

**Table 4: Part VI.1- Summary of safety concerns**

| **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 authorisation or specific obligation of Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde tabletten.

**II.C.2 Other Studies in Post-Authorisation Development Plan**

There are no studies required for Fexofenadine HCl Viatris 120 mg and 180 mg filmomhulde