Part VI: Summary of the risk management plan by product

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Summary of safety concerns	
Important identified risks	• Systemic hypersensitivity reactions
Important potential risks	• Cardiovascular events (i.e. tachycardia and palpitations)
Missing information	• Use in pregnant and lactating women • Use in children less than 12 years of age

VI.1.2 Table of on-going and planned studies in the Post-authorisation Pharmacovigilance Development Plan

Not applicable.

VI.1.3 Summary of Post authorisation efficacy development plan

Not applicable.

VI.1.4 Summary table of risk minimisation measures

Safety concern	**Routine risk minimisation measures**	**Additional risk minimisation measures**
IMPORTANT IDENTIFIED RISKS		
Systemic hypersensitivity reactions	Listed in section **4.8**.	None proposed
IMPORTANT POTENTIAL RISKS		
Cardiovascular events (i.e. tachycardia and palpitations)	Warning in section **4.4** and listed in section **4.8** of the SmPC.	None proposed
MISSING INFORMATION		
Use in children less than12 years of age	Indication in section **4.1** and warnings in sections **4.2** and **4.4**.	None proposed
Use in pregnant and lactating women	Warning in section **4.6** of the SmPC.	None proposed

VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Fexofenadine hydrochloride is a non-sedating H1-antihistamine.

Fexofenadine 120 mg film-coated tablets are indicated for symptomatic relief of seasonal allergic rhinitis.

Seasonal allergic rhinitis

Rhinitis is an inflammation of the nasal membranes that is characterized by sneezing, nasal congestion, nasal itching, and rhinorrhoea, in any combination. Inflammation of the mucous membranes is characterized by a complex interaction of inflammatory substances.

Allergic rhinitis is the most common form of rhinitis. It is an extremely common condition, affecting approximately 20% of the population. Although allergic rhinitis itself is not life-threatening (unless accompanied by severe asthma or anaphylaxis), morbidity from the condition can be significant.

Throughout the world, the prevalence of allergic rhinitis has slightly escalated. Currently, approximately 10 to 30% of adults and 40% of children are affected. The European Community Respiratory Health survey recorded a prevalence of 10 to 41% in adults with allergic rhinitis.

Fexofenadine 180 mg film-coated tablets are indicated for symptomatic relief of chronic idiopathic urticaria.

Chronic idiopathic urticaria

Urticaria is not a single disease but a reaction pattern with the condition being defined as chronic if it persists for longer than 6 weeks. The mast cell degranulation results in extravasation of plasma into the dermis; urticaria is characterized by hives or wheals, which are oedematous and pruritic.

The mast cell is the primary agent in the pathogenesis of urticaria. Mast cell stimulation results in the release of both preformed (histamine) and newly formed (prostaglandin) substances from cytoplasmic granules, which cause wheal formation, vasodilatation, and erythema.

Studies aiming to assess the exact number of people having chronic urticaria in the general population are still missing. It has been estimated that this disease affects about 0.1% of the general population but the real number of people having chronic urticaria possibly exceeds this amount. Chronic urticaria occurs predominantly in adults; women are more commonly affected than men and the disease frequently shows a familiar pattern.

VI.2.2 Summary of treatment benefits

Based on the available data from clinical studies and clinical experience of several years, fexofenadine represents an effective drug in the symptomatic relief of seasonal allergic rhinitis and chronic idiopathic urticaria.

If administered as indicated in the Summary of Product Characteristics and taking into account the contraindications, the warnings and precautions, fexofenadine can be considered effective in the approved indications and generally well tolerated.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergy (hypersensitivity) reactions	Patients taking fexofenadine may rarely experience allergic skin reactions such as eczema, hives and itching, unexpected swelling (oedema), chest tightness, shortness of breath and flushing.	Do not take fexofenadine if you are allergic to fexofenadine or any of the other ingredients of this medicine.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Heart and blood vessels events (i.e. faster heartbeat, feeling your heartbeat)	Patients should be warned that, antihistamines as a drug class, have been associated with faster heart beat (tachycardia) and sensation of feeling their heartbeat (palpitations).

Missing information

Risk	What is known
Use in children less than12 years of age	The efficacy and safety of fexofenadine has not been studied in children under 12.
Use in pregnant and lactating women	There are no adequate data from the use of fexofenadine in pregnant women. Fexofenadine should not be used during pregnancy unless clearly necessary. There are no data on the content in human milk after administration of fexofenadine. However, when terfenadine was administered to nursing mothers, fexofenadine was found to cross into human breast milk. Therefore, it is not recommended to administer fexofenadine to breastfeeding mothers.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the Patient Information Leaflet (PIL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.