7 Part VI: Summary of activities in the risk management plan by product

7.1 Part VI.1 Elements for summary tables in the EPAR

Table 7-1 Part VI.1.1 Summary table of safety concerns

Important identified risks	Renal dysfunction as a consequence of dual renin-angiotensin-aldosterone system blockade Sepsis Foetotoxicity Hypoglycaemia (in diabetic patients)
Important potential risks	Rhabdomyolysis Increase of hepatic related adverse reactions in the Japanese population Interstitial lung diseases Severe cutaneous reactions Suicide/self-injury Malignancies
Important missing information	None

Table 7-2 Part VI.1.2 Table of on-going and planned additional PhV studies/activities in the Pharmacovigilance Plan

None

Table 7-3 Part VI.1.3 Summary of Post authorization efficacy development plan

None

Table 7-4 Part VI.1.4 Summary table of risk minimization measures

Safety concern	Routine risk minimization measures	Additional risk minimization measures
Renal dysfunction as a consequence of dual renin-angiotensin-aldosterone system blockade	Reference is given in the sections 4.4 "Special warnings and precautions for use" and 4.8 "Undesirable effects" of the SmPC.	None
Sepsis	Reference is given in the section 4.8 "Undesirable effects" of the SmPC.	None
Foetotoxicity	Reference is given in section 4.6 "Fertility, pregnancy and lactation" of the SmPC.	None
Hypoglycaemia (in diabetic patients)	Reference is given in sections 4.4 "Special warnings and precautions for use" and 4.8 "Undesirable effects" of the SmPC.	None
Rhabdomyolysis	Currently available data do not support the need for risk minimization	None
Increase of hepatic related adverse reactions in the Japanese population	Reference is given in the section 4.8 "Undesirable effects" of the SmPC.	None
Interstitial lung diseases	Reference is given in section 4.8 "Undesirable effects" of the SmPC.	None
Severe cutaneous reactions	Reference is given in section 4.8 "Undesirable effects" of the SmPC.	None
Suicide/self-injury	Currently available data do not support the need for risk minimization	None

7.2 Part VI.2 Elements for a Public Summary

7.2.1 Part VI.2.1 Overview of disease epidemiology

High blood pressure or hypertension is a common disease. A quarter of the adult population is affected. Hypertension itself has no symptoms but it can lead to serious diseases like stroke or coronary artery disease if left untreated.

7.2.2 Part VI.2.2 Summary of treatment benefits

7.2.2.1 Current (gold) standards of treatment

Current treatment of hypertension includes lifestyle changes (e.g. reduction of overweight and stress, smoking cessation, regular exercise) and high blood pressure medications (antihypertensives), e.g. diuretics (water pills), Angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers, Beta blockers, Calcium channel blockers and Renin inhibitors.

7.2.2.2 Where the medicinal product fits in the therapeutic armamentarium (i.e. 1st line, relapse, etc.)

Telmisartan belongs to the group of Angiotensin II receptor blockers. Angiotensin II is a naturally occurring hormone in the human body that causes the blood vessels to constrict, thus making the blood pressure higher. Telmisartan lowers blood pressure by specially blocking the action of angiotensin II, and thus relaxing the blood vessels. As a result blood pressure is lowered.

7.2.2.3 Post-authorization data which impacts on efficacy

This is a generic product. The efficacy profile is based on the originator/ reference product. No post-authorization data is available which is known to impact the efficacy of the product.

7.2.3 Part VI.2.3 Unknowns relating to treatment benefits

None

7.2.4 Part VI.2.4 Summary of safety concerns

Table 7-5 Important identified risks

Risk	What is known	Preventability
Renal dysfunction as a consequence of dual renin-angiotensin-aldosterone system blockade	As a consequence of inhibiting the renin-angiotensin-aldosterone system changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system.	Dual blockade of the renin-angiotensin-aldosterone system (e.g. by administering telmisartan with other blockers of the renin-angiotensin-aldosterone system) is not recommended. Close monitoring of renal function is advisable if co-administration is considered necessary.
Sepsis	In the PRoFESS trial, an increased incidence of sepsis was observed with telmisartan compared with placebo.	N/A, the observed increased occurrence rate of sepsis associated with the use of telmisartan may be either a chance finding or related to a mechanism not currently known.
Foetotoxicity	Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is	Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Risk	What is known	Preventability
	known to induce human foetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia).	Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended. Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension.

Table 7-6 Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Rhabdomyolysis (muscle breakdown)	Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers. Muscle breakdown resulting in kidney damage can be serious and may become a potentially life-threatening condition.
Increase of hepatic related adverse reactions in the Japanese population	Most cases of hepatic function abnormal / liver disorder from post-marketing experience occurred in patients in Japan, who are more likely to experience these adverse reactions.
Interstitial lung diseases	Cases of interstitial lung disease have been reported from post-marketing experience in temporal association with the intake of telmisartan. However, a causal relationship has not been established.
Severe cutaneous reactions	Angioedema (also with fatal outcome), eczema, erythema, urticaria, drug eruption and toxic skin eruption have been reported in rare cases.
Suicide/self-injury	Cases of suicide attempts have been reported. However, the data are too limited to conclude that there is an increased risk of suicide/self-injury.
Malignancies	Cases of malignancies have been reported. However, the data are too limited to conclude that there is an increased risk of malignancies.

7.2.5 Part VI.2.5 Summary of additional risk minimization measures by safety concern

None

7.2.6 Part VI.2.6 Planned post authorization development plan

None

7.2.7 Part VI.2.7 Summary of changes to the Risk Management Plan over time

N/A for version 1