VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Not applicable. This is a generic application. Our SmPC comply with the innovator product regarding indications and adverse events.

VI.2.2 Summary of treatment benefits

Not applicable. This is a generic application. Our SmPC comply with the innovator product regarding indications and adverse events.

VI.2.3 Unknowns relating to treatment benefits

Not applicable. This is a generic application. Our SmPC comply with the innovator product regarding indications and adverse events.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Sepsis	Sepsis (often called "blood poisoning"), is a severe infection with whole-body inflammatory response, rapid swelling of the skin and mucosa (angioedema). These side effects are rare (may affect up to 1 in 1,000 people).	Yes, by monitoring for early symptoms and proper treatment.
Kidney impairment in case of co-administration of 2 different drugs which affect renin-angiotensin-aldosteron system	Changes in kidney function have been reported in some individuals who were treated with another medicine which affect renin-angiotensin-aldosteron system.	Yes, by monitoring of biochemical laboratory tests.
Kidney impairment in case of co-administration of 2 different drugs which affect renin-angiotensin-aldosteron system	Changes in kidney function have been reported in some individuals who were treated with another medicine which affect renin-angiotensin-aldosteron system.	Yes, by monitoring of biochemical laboratory tests.
Serious harm to baby if mother is after the third month of pregnancy	When used in the second or third trimester of pregnancy, medicine can cause injury and even death to the fetus.	Women who are taking these medicines should tell their doctor if they think they are or might become pregnant. Patients who have any questions or concerns should talk to their doctor or pharmacist.
Low blood sugar levels	It may affect up to 1 in 1,000 people. Low blood sugar levels occur mainly in diabetic patients and patients with abnormal glucose tolerance.	Yes, by monitoring for early symptoms and proper dosage adjustement of antidiabetics**.**

Important potential risks:

Risk	What is known (Including reason why it is considered a potential risk)
Increase in hepatic-related side effects in the Japanese population	Japanese patients are more likely to experience these side effect. Most cases of hepatic function abnormal / liver disorder from

	post-marketing experience with telmisartan occurred in Japanese patients.
Rhabdomyolysis	There are no data suggesting causal relationship between telmisartan+hydrochlorothiazide and rhabdomyolysis. Rhabdomyolysis is potentially life threatening muscle damage and due to the seriousness of the condition and its potential public health impact rhabdomyolysis is monitored to detect potential relationship between telmisartan use and rhabdomyolysis.
Progressive scarring of lung tissue (interstitial lung disease)	Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.
Skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, or blistering and peeling of the top layer of skin (toxic epidermal necrolysis)	The frequency of of side effects cannot be estimated from available data. In case of early symptoms these serious skin disorders can be preveted.
Suicide/self-injury	At the moment no data suggesting causal relationship between telmisartan+hydrochlorothiazide but due to seriousness of the condition and its potential public health impact suicide/self-injury risk is monitored to detect potential relationship between telmisartan use and cancer risk.
Risk of new cancers	The CHMP reviewed the risk of new cancers with the use of angiotensin II receptor antagonists (ARBs) and concluded that the existing evidence did not support a link between the use of ARBs and the occurrence of new cancers and that the benefits of ARBs continue to outweigh their risks. The CHMP did not recommend any changes to the prescribing information for these medicines. Due to the seriousness of the condition and its potential public health impact cancer risk is monitored to detect potential relationship between telmisartan use and cancer risk.

Missing information

No missing information has been identified.

VI.2.5 Summary of additional 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 package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for this product can be found at the agency's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable. No postauthorisation studies are planned.

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

Table: Major changes to the Risk Management Plan over time

Version	***Date***	***Safety concerns***	***Comment***
2.0	26.9.2014 At time of variation According to Article 31 referrals (Renin-angiotensin-system (RAAS)-acting agents)	Renal dysfunction, hypotension and hyperkalaemia as consequence of dual RAAS blockade	The previous term »renal dysfunction as consequence of dual RAAS blockade" was updated to »renal dysfunction, hypotension and hyperkalaemia as consequence of dual RAAS blockade"