VI.2 Elements for a Public Summary

/…/ 80 mg/25 mg tablets

VI.2.1 Overview of disease epidemiology

High blood pressure (hypertension), defined as blood pressure (BP) > 140/90 mm Hg, is estimated to affect 20 % of the adult population worldwide. In North America, 28 % of the population is affected, in European Countries 44 %. The risk to suffer from hypertension increases strongly with advanced age. 50 % of individuals older than 60 years suffer from hypertension. In the younger population, more men than women are affected, in patients over 70 years, more women are affected than men.
Patients suffering from increased blood pressure are at an increased risk of developing other cardiovascular diseases and fatal stroke.

VI.2.2 Summary of treatment benefits

/…/ is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

/…/ **is used to** treat high blood pressure (essential hypertension) in adults whose blood pressure is not adequately controlled by <Product name> 80/12.5 mg or in patients who have been previously stabilised by telmisartan and hydrochlorothiazide given separately.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Severe life-threatening infection (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) but are extremely serious. If these effects are not treated they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for /…/. The event was not observed in clinical trials and may have happened by chance or could be related to a mechanism currently not known.	You should see your doctor immediately if you experience any of the symptoms mentioned.
Renal dysfunction as consequence of use of two medicines acting on the same hormone system that regulates blood pressure (Renal dysfunction as consequence of dual RAAS blockade)	If combining medicinal products that affect this hormone system, hypotension, syncope, hyperkalaemia, and changes in renal function (including acute renal failure) can occur more frequently. The combination is not recommended.	Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will consider close monitoring of renal function if co-administration is considered necessary.
Serious harm to unborn child (Fetotoxicity)	/.../ is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.	You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking /.../ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of /.../.

Decreased blood sugar levels (Hypoglycaemia)	In diabetic patients taking hydrochlorothiazide alone irregular blood sugar levels have been observed. Frequency cannot be estimated from the available data.	If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Increase in hepatic-related adverse reactions in the Japanese population	Most cases of abnormal hepatic function or liver disorders from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience these adverse reactions.
Rhabdomyolysis	Rhabdomyolysis is a severe disease of the skeletal muscles. Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
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	Blistering and peeling of the top layer of skin (so called ‘toxic epidermal necrolysis’) have been reported in patients taking hydrochlorothiazide. The frequency cannot be estimated from the available data.
Suicide/self-injury	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Malignancies	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.

Missing information

Risk	What is known (Including reason why it is considered a potential risk)
none	Not applicable

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) 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 medicine can be found in the EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

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

Not applicable.