VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Cardiovascular prevention
The prevention of cardiovascular disease represents one of the most important aspects of preventive medicine today. The terms primary and secondary prevention have been used to encompass patients with or without established clinical evidence of cardiovascular disease. Cardiovascular disease (CVD) causes more than half of all deaths across the European Region and causes 46 times the number of deaths and 11 times the disease burden caused by AIDS, tuberculosis and malaria combined in Europe. 80% of premature heart disease and stroke is preventable.

Hypertension
Worldwide, raised blood pressure is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths. This accounts for 57 million disability adjusted life years (DALYS) or 3.7% of total DALYS. Blood pressure levels have been shown to be positively and continuously related to the risk for stroke and coronary heart disease. In some age groups, the risk of cardiovascular disease doubles for each increment of 20/10 mmHg of blood pressure, starting as low as 115/75 mmHg. In addition to coronary heart diseases and stroke, complications of raised blood pressure include heart failure, peripheral vascular disease, renal impairment, retinal hemorrhage and visual impairment. Globally, the overall prevalence of raised blood pressure in adults aged 25 and over was around 40% in 2008.

VI.2.2 Summary of treatment benefits

Cardiovascular prevention
Telmisartan has been studied in patients aged 55 years or over who have had heart or artery disease, had had a stroke, or had diabetes and were at high risk of cardiovascular problems. Telmisartan was compared with ramipril (another medicine to prevent cardiovascular problems) and with the combination of both medicines. The main measure of effectiveness was the reduction in the number of patients who died or were admitted to hospital, or who had a heart attack or stroke.

Hypertension
In patients with hypertension telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. The maximum reduction in blood pressure is generally attained 4 to 8 weeks after the start of treatment and is sustained during long-term therapy.

The efficacy of telmisartan has been demonstrated in several well-controlled studies. A summary of these studies can be found in the EPAR of the reference product Micardis ®.

VI.2.3 Unknowns relating to treatment benefits

Telmisartan is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

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 and eventhough there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs.

Because no information is available regarding the use of telmisartan during breast-feeding, telmisartan is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Serious harm to unborn child (Foetotoxicity)	Telmisartan is not recommended in early pregnancy and should not be taken during second and third trimester of pregnancy, as it may cause serious harm to the baby.	Patient´s have to tell their doctor if they think they are (or might become) pregnant. Treatment with telmisartan should be stopped before pregnancy or as soon as the patient is aware of the pregnancy. In these situations alternative medication should be used instead of telmisartan.
Renal dysfunction as a consequence of use of two medicines acting on the same hormone system that regulates blood pressure (Renal dysfunction as a consequence of dual renin-angiotensin-aldosterone system blockade)	Concomitant use of telmisartan with an ACE-inhibitor (for example enalapril, lisinopril, ramipril) or aliskiren in particular in patients with diabetes or impaired kidney function may cause changes in renal function (including acute renal failure).	Aliskiren should not be used concomitantly with telmisartan. Concomitant use with ACE-inhibitor (for example enalapril, lisinopril, ramipril) is not recommended; if the treatment is considered necessary, frequent close monitoring of kidney function, electrolytes (e.g. potassium) and blood pressure is recommended.
Blood poisoning (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 can be fatal. Increased incidence of sepsis has been observed with telmisartan. This observed increased occurrence rate may be either a chance finding or related to a mechanism not currently known.	If the patient experiences rapid swelling of the skin and mucosa (angioedema), the patient should stop taking the medicine and see the doctor immediately.
Decreased blood sugar levels (in diabetic patients) (Hypoglycaemia (in diabetic	In diabetic patients hypoglycaemia may occur under telmisartan treatment.	Diabetic patients are advised to talk to his/her doctor of the condition before the treatment

Risk	What is known	Preventability
patients))		with telmisartan. For diabetic patients who receive telmisartan an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Rhabdomyolysis	During telmisartan treatment intercurrent event of a severe disease of the skeletal muscles (rhabdomyolysis) may increase the risk for hyperkalaemia.
Increase of hepatic related adverse reactions in the Japanese population	Most cases of hepatic function abnormal / liver disorder from post-marketing experience with telmisartan occurred in patients in Japan, who are more likely to experience these adverse reactions.
Malignancies	Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists (ARBs). The European Medicines Agency (EMA) has reviewed the possible link between the use of ARBs and the occurrence of new cancers (particularly lung cancer). The EMA concluded that the evidence does not support any increased risk of cancer in patients using these medicines.

Missing information

Risk	What is known
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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 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 medicinal product can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

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

Not applicable.

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

Not applicable.