Olmesartan medoxomil STADA

10.11.2015, VersioN V1.2

PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Olmesartan medoxomil STADA 10 mg film-coated tablets.
Olmesartan medoxomil STADA 20 mg film-coated tablets.
Olmesartan medoxomil STADA 40 mg film-coated tablets.

VI.2.1 Overview of disease epidemiology

High blood pressure
Hypertension is a chronic medical condition in which the blood pressure in the arteries is raised. Hypertension puts persistent strain on the heart, leading to hypertensive heart disease and coronary artery disease if untreated. High blood pressure can damage blood vessels in organs such as the heart, kidneys, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Essential hypertension, i.e. hypertension where high blood pressure is not caused by another disease, is the most common form of hypertension, accounting for 90–95% of all cases. In Europe, hypertension occurs in about 30-45% of people as of 2013, with an increase with age. As there are no particular symptoms which occur due to raised blood pressure, blood pressure measurements must be done at regular intervals. Treatment options include lifestyle modifications (such as dietary changes, physical exercise, and weight loss) and treatment with other antihypertensive medications or combinations thereof.

VI.2.2 Summary of treatment benefits

Olmesartan medoxomil Stada contains the active ingredient olmesartan which belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Olmesartan medoxomil Stada is used for the treatment of high blood pressure (also known as ‘hypertension’). High blood pressure can damage blood vessels in organs such as the heart, kidneys, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Usually high blood pressure has no symptoms. It is important to have your blood pressure checked to prevent damage occurring.

High blood pressure can be controlled with medicines such as Olmesartan medoxomil Stada tablets. Your doctor has probably also recommended that you make some changes in your lifestyle to help lower your blood pressure (for example losing weight, giving up smoking, reducing the amount of alcohol you drink and reducing the amount of salt in your diet). Your doctor may also have urged you to take regular exercise, such as walking or swimming. It is important to follow this advice from your doctor.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of olmesartan in children and adolescents below 18 years has not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Serious harm to unborn child (Fetotoxicity upon olmesartan exposure in 2nd and/or 3rd trimester of pregnancy)	Scientific evidence regarding the risks of olmesartan to the unborn child is inconclusive but a small increase in risk cannot be excluded. Olmesartan should therefore not be initiated during pregnancy. Unless continued therapy with olmesartan is considered essential, patients planning pregnancy should be changed to alternative treatment.	You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking olmesartan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of olmesartan.
Increased potassium levels (Hyperkalaemia)	You have a higher risk of developing high potassium levels if you are: A diabetic patient with impaired kidney function and over 70 years of age If you are taking another drug which acts on the same target system as olmesartan (e.g. enalapril) and/or potassium supplements If you are taking non-steroidal anti-inflammatory medicinal drugs (NSAIDs) used for pain relief (e.g. ibuprofen) If you are taking immunosuppressants (cyclosporin or tacrolimus) If you are taking an antibiotic trimethoprim. If you are taking a drug(s) which help to excrete excessive body fluid (potassium sparing diuretics)	Tell your doctor if you are: A diabetic patient with impaired kidney function and over 70 years of age If you are taking another drug which acts on the same target system as olmesartan(e.g. enalapril) and/or potassium supplements If you are taking non-steroidal anti-inflammatory medicinal drugs (NSAIDs) used for pain relief (e.g. ibuprofen) If you are taking immunosuppressants (cyclosporin or tacrolimus) If you are taking an antibiotic trimethoprim. If you are taking a drug(s) which help to excrete excessive body fluid (potassium sparing diuretics) Contact your doctor **immediately** if you experience any of the following symptoms: Muscle fatigue Weakness Paralysis Abnormal heart rhythms (arrhythmias) Nausea

Increase in adverse effects in patients with conditions resulting in impaired bile flow from the liver (Increase in adverse effects risk in patients with biliary obstructive disorders)	Olmesartan is mostly eliminated from the organism with the bile (secreted by the liver). Olmesartan should therefore not be given to patients with conditions resulting in impaired bile flow from the liver.	Tell your doctor if you have or have ever suffered from any liver problems. The doctor may need to adjust your olmesartan dose in case of liver problems or even stop the drug. Tell your doctor **immediately** if you notice any of the following overdose symptoms: Low blood pressure Fast heart rate Slow heart rate Shortness of breath Fatigue Confusion Nausea
Risks associated with simultaneous treatment with other blood pressure lowering drugs (Concomitant treatment with other renin-angiotensin-system (RAS)-acting agent(s))	When the same physiological system is inhibited by olmesartan and another blood pressure drug (e.g. enalapril) which is taken simultaneously, there is a risk of low blood pressure, fainting, high blood potassium and changes in kidney function. Taking olmesartan with another drug which inhibits the same physiological system is therefore not recommended.	Tell your doctor what other medicines you are taking (including the medicines which are available over-the-counter). Where the doctor decides to continue your therapy with a drug which acts on the same system as olmesartan, the doctor will closely monitor your lab values to assure that you do not experience an adverse event.
Lithium toxicity during concomitant use with olmesartan	Reversible increases in serum lithium concentrations and toxicity have been reported during simultaneous administration of lithium with the drug class that olmesartan belongs to. This may lead to various lithium adverse effects, such as tremor, blurred vision and muscle stiffness. Therefore use of olmesartan l and lithium in combination is not recommended.	Tell your doctor if you are taking lithium. Your doctor may still recommend simultaneous treatment with olemsartan and lithium, in which case careful monitoring of serum lithium levels will be undertaken to avoid toxicity. Tell your doctor **immediately** if you notice any of the following symptoms: hallucinations seizure fever with muscle stiffness fast or uneven heartbeats;, nausea, vomiting, tremor lack of coordination blurred vision

Intestinal disease (Sprue-like enteropathy)	In very rare cases severe, chronic diarrhoea with substantial weight loss has been reported in patients taking olmesartan few months to years after drug initiation, possibly caused by a localised delayed hypersensitivity reaction. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss. The enteropathy may develop months to years after starting olmesartan, and sometimes requires hospitalisation.	Tell your doctor **immediately** if you notice any of the following symptoms: severe, chronic diarrhea with substantial weight loss

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Potential interaction with medicinal products affecting potassium levels	Simultaneous use of potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other drugs that may increase serum potassium levels (e.g. heparin) may lead to increases in serum potassium. Such concomitant use is therefore not recommended.
Use in the sub-populations with renal artery, atortic, or mitrial valve stenosis	In patients with severe congestive heart failure or kidney disease, treatment with other drugs that affect the same system as olmesartan has been associated with acute hypotension, high levels of nitrogen in blood, urinary disorders or, rarely, acute kidney failure.

Missing information

Risk	**What is known**
Use in paediatric patients	The safety and efficacy of olmesartan in children and adolescents below 18 years has not been established.
Use in patients with severe kidney or liver impairment	The use of olmesartan in patients with severe kidney or liver impairment is not recommended, since there is only limited experience in this patient group.

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.
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.