Olmestad Comp Comp 20 mg/12.5 mg film-coated tablets
Olmestad Comp Comp 20 mg/25 mg film-coated tablets

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PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Olmestad Comp 20 mg/12.5 mg film-coated tablets
Olmestad Comp 20 mg/25 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

Olmestad Comp contains two active substances, olmesartan medoxomil and hydrochlorothiazide, that are used to treat high blood pressure (hypertension):

- Olmesartan medoxomil is one of a group of medicines called angiotensin II-receptor antagonists. It lowers blood pressure by relaxing the blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics (“water tablets”). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

You will only be given Olmestad Comp if olmesartan medoxomil alone has not adequately controlled your blood pressure. When given together, the two active substances in Olmestad Comp help to lower blood pressure more than if either of them were given alone.

You may already be taking medicines to treat your high blood pressure, but your doctor may want you to take Olmestad Comp to lower it more.

High blood pressure can be controlled with medicines such as Olmestad Comp 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/ hydrochlorothiazide 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**
Allergic reactions (Hypersensitivity)	Allergic reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history. These allergic reactions are rarely life-threatening.	Tell your doctor **immediately** if you notice any of the following symptoms: • any skin changes • swollen eyes, lips, hands and feet • swelling of the mouth, throat or tongue • abdominal pain, nausea and vomiting.
Kidney function impairment (Renal impairment)	Kidney dysfunction or kidney failure may occur rarely (from 1 in 1,000 to 1 in 10,000 patients) with Olmestad Comp. Olmestad Comp should not be used in patients with severe kidney impairment. There is no experience of the administration of olmesartan/ hydrochlorothiazide in patients with a recent kidney transplantation.	Your doctor will monitor your kidney function at regular intervals, as well as your potassium and uric acid levels. It is important that you attend all your appointments and tests.

Decreased potassium, calcium, sodium levels and symptomatic increased levels of uric acid (Hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia)	Hydrochlorothiazide can cause various fluid or electrolyte imbalance (including decreased potassium, calcium, sodium levels and symptomatic increased levels of uric acid). The risk decreased potassium is greatest in patients with cirrhosis of the liver, in patients experiencing fast water loss, in patients who are receiving inadequate oral intake of electrolytes and in patients receiving simultaneous therapy with corticosteroids.	Tell your doctor **immediately** if you notice any of the following overdose symptoms: • dryness of the mouth • thirst • weakness • lethargy • drowsiness • restlessness • muscle pain or cramps • muscular fatigue • low blood pressure • very small urine volumes • increased heart rate • gastrointestinal disturbances, such as nausea or vomiting
Moderate and severe liver impairment; Increase in adverse effects in patients with conditions resulting in impaired bile flow from the liver (Moderate and severe hepatic impairment, cholestasis and biliary obstructive disorders)	Olmesartan accumulates in patients who have impaired liver function. The dose in these patients may differ; some patients may need to stop the drug. 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 Olmestad Comp 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

Serious harm to unborn child (2nd and 3rd trimester of pregnancy)	Scientific evidence regarding the risks of olmesartan and hydrochlorothiazide to the unborn child is inconclusive but a small increase in risk cannot be excluded. Olmestad Comp should therefore not be initiated during pregnancy. Unless continued therapy with Olmestad Comp 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 Olmestad Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmestad Comp.
Risks associated with simultaneous treatment with other blood pressure lowering drugs (Combined use of renin-angiotensin-system (RAS)-acting agents leading to increased risk of hyperkalaemia (high blood potassium levels), low blood pressure and kidney failure, compared with using one RAS-acting agent alone)	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/hydrochlorothiazide (Lithium toxicity with concomitant use of olmesartan/hydrochlorothiazide)	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. In addition, kidney elimination of lithium from the body is reduced by hydrochlorothiazide and consequently the risk of lithium toxicity may be increased. Therefore use of Olmestad Comp and lithium in combination is not recommended.	Tell your doctor if you are taking lithium. Your doctor may still recommend simultaneous treatment with Olmestad Comp 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.
Increased risk of fatal events from cardiovascular causes in patients with type 2 diabetes with additional cardiovascular risks	In patients with type 2 diabetes who also have additional cardiovascular risks (e.g. cardiac failure), the risk of fatal events cannot at present be elucidated.
Acute myopia, secondary acute angle-closure glaucoma	Risk of various eye disorders (myopia and worsening of pre-existing myopia, as well as angle-closure glaucoma) cannot be estimated from the available data.

Missing information

Risk	**What is known**
Use in paediatric patients	The safety and efficacy of olmesartan/ hydrochlorothiazide in children and adolescents below 18 years has not been established.

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.