

# OLSAR-AH

## For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for OLSAR-AH (Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablets)

[Please refer the complete prescribing information for details].

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** OLSAR-AH is a combination of an angiotensin II receptor antagonist, olmesartan medoxomil, a calcium channel blocker, amlodipine besilate and a thiazide diuretic, hydrochlorothiazide. The combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than each component alone

**INDICATIONS:** It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**DOSAGE AND ADMINISTRATION:** OLSAR-AH is indicated for the treatment of essential hypertension.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients.

**WARNINGS & PRECAUTIONS:** ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems, Aliskiren, Kidney problems or a kidney transplant, Liver disease, Heart failure or problems with your heart valves or heart muscle, Severe vomiting, diarrhoea, treatment with high doses of “water tablets” (diuretics) or if you are on a low salt diet, Increased levels of potassium in your blood, Problems with your adrenal glands (hormone-producing glands on top of the kidneys), Diabetes, Lupus erythematosus (an autoimmune disease), Allergies or asthma, Skin reactions such as sunburn or rash after being in the sun or using a sunbed, If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking OLSAR-AH.

**DRUG INTERACTIONS:** *Potential interactions related to the OLSAR-AH combination:*  
*Concomitant use not recommended:* Lithium, *Concomitant use requiring caution:* Baclofen.  
*Concomitant use to be taken into account:* Amifostine. *Concomitant use not recommended:* ACE-inhibitors, angiotensin II receptor blockers or aliskiren. *Concomitant use requiring caution:* CYP3A4 inhibitors. *Concomitant use not recommended:* Medicinal products affecting potassium levels. *Concomitant use requiring caution:* Calcium salts. Others; Anticholinergic agents, Metformin, Beta-blockers and diazoxide, Amantadine, Salicylates, Tetracyclines.

**ADVERSE REACTIONS:** Allergic reactions with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur. **Common** (*May affect less than 1 in 10 people*) : Upper respiratory tract infection; sore throat and nose; urinary tract infection; dizziness; headache; awareness of heartbeat; low blood pressure; nausea; diarrhoea; constipation; cramps; joint swelling; feeling more of an urge to pass urine; weakness; ankle swelling; tiredness; abnormal laboratory values. Bronchitis; stomach and gut infection; vomiting; increased blood sugar; sugar in urine; confusion; feeling sleepy; visual disturbance (including double vision and blurred vision); runny or stuffy nose; sore throat; difficult breathing; cough; abdominal pain; heartburn; stomach discomfort; flatulence; pain in the joints or bones; back pain; skeletal pain; blood in the urine; flu-like symptoms; chest pain; pain. **Very common** (*May affect more than 1 in 10 people*) Oedema (fluid retention) **Uncommon** (*May affect less than 1 in 100*

*people*) Dizziness on standing up; vertigo; fast heartbeat; feeling faint; redness and warm feeling of the face; cough; dry mouth; muscular weakness; inability to get or maintain an erection. Reduced number of a type of blood cells known as platelets, which can result in bruising easily or a prolonged bleeding time; anaphylactic reactions; abnormally reduced appetite (anorexia); problems sleeping; irritability; mood changes including feeling anxious; feeling “down” or depressed; shiver; sleep disturbances; distorted sense of taste; loss of consciousness; reduced sense of touch; tingling sensations; worsening of shortsightedness; ringing in the ears (tinnitus); angina (pain or uncomfortable feeling in the chest, known as angina pectoris); irregular heart beat; rash; loss of hair; allergic inflammation of the skin; redness of skin; purplish spots or patches on the skin due to small haemorrhages (purpura); discolouration of the skin; red itchy bumps (hives); increased sweating; itching; eruption of the skin; skin reactions to light such as sunburn or rash; muscle pain; problems to pass urine; feeling urge to pass urine at night; breast enlargement in men; decreased sexual desire; swelling of the face; feeling unwell; weight increase or decrease; exhaustion. **Rare** (*May affect less than 1 in 1,000 people*) Swollen and sore salivary glands; reduced number of white cells in the blood, which could increase the risk of infections; low red blood cell count (anaemia); bone marrow damage; restlessness; feeling uninterested (apathy); fits (convulsions); objects you look at appearing yellow; dry eyes; blood clots (thrombosis, embolism); fluid accumulation in the lungs; pneumonia; inflammation of blood vessels and small blood vessels in the skin; inflammation of the pancreas; yellowing of the skin and eyes; acute inflammation of the gall bladder; symptoms of lupus erythematosus such as rash, joint pains and cold hands and fingers; severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis), sometimes life-threatening; impaired movement; acute kidney failure; non-infectious kidney inflammation; poor kidney function; fever. **Very Rare** (*May affect less than 1 in 10,000 people*) High muscle tension; numbness of hands or feet; heart attack; inflammation of the stomach; thickening of the gums; blockage in the gut; inflammation of the liver. **Not Known** Decrease in vision or eye pain (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma). Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk. Skin and lip cancer (Non-melanoma skin cancer)

**MARKETED BY:**



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(Additional information is available on request)