

## Package leaflet: Information for the patient

Olmesartan /Amlodipine Mylan 20 mg/5 mg film-coated tablets  
Olmesartan /Amlodipine Mylan 40 mg/5 mg film-coated tablets  
Olmesartan /Amlodipine Mylan 40 mg/10 mg film-coated tablets

olmesartan medoxomil/amlodipine

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Olmesartan /Amlodipine Mylan is and what it is used for
2. What you need to know before you take Olmesartan /Amlodipine Mylan
3. How to take Olmesartan /Amlodipine Mylan
4. Possible side effects
5. How to store Olmesartan /Amlodipine Mylan
6. Contents of the pack and other information

### **1. What Olmesartan /Amlodipine Mylan is and what it is used for**

Olmesartan /Amlodipine Mylan contains two substances called olmesartan medoxomil and amlodipine (as amlodipine besilate). Both of these substances help to control high blood pressure.

- Olmesartan medoxomil belongs to a group of medicines called angiotensin-II receptor antagonists which lower blood pressure by relaxing the blood vessels.
- Amlodipine belongs to a group of substances called calcium channel blockers. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening thereby also reducing blood pressure.

The actions of both these substances contribute to stopping the tightening of blood vessels, so that blood vessels relax and blood pressure decreases.

Olmesartan /Amlodipine Mylan is used for the treatment of high blood pressure in patients whose blood pressure is not controlled enough with either olmesartan medoxomil or amlodipine alone.

### **2. What you need to know before you take Olmesartan /Amlodipine Mylan**

#### **Do not take Olmesartan /Amlodipine Mylan:**

- if you are allergic to olmesartan medoxomil or to amlodipine or a special group of calcium channel blockers, the dihydropyridines, or to any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, talk to your doctor before taking Olmesartan /Amlodipine Mylan.

- if you are more than 3 months pregnant (It is also better to avoid Olmesartan /Amlodipine Mylan in early pregnancy - see section Pregnancy and breast-feeding).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have severe liver problems, if bile secretion is impaired or drainage of bile from the gallbladder is blocked (e.g. by gallstones), or if you are experiencing any jaundice (yellowing of the skin and eyes).
- if you have very low blood pressure.
- if you are suffering from insufficient blood supply to your tissues with symptoms like e.g. low blood pressure, low pulse, fast heartbeat (shock, including cardiogenic shock). Cardiogenic shock means shock due to severe heart troubles.
- if the blood flow from your heart is obstructed (e.g. because of the narrowing of the aorta (aortic stenosis)).
- if you suffer from low heart output (resulting in shortness of breath or peripheral swellings) after a heart attack (acute myocardial infarction).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Olmesartan /Amlodipine Mylan.

**Tell your doctor** if you are taking any of the following medicines used to treat high blood pressure:

- an angiotensin-converting-enzyme-inhibitor (ACE-inhibitor; for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading ‘Do not take Olmesartan /Amlodipine Mylan’.

**Tell your doctor** if you have any of the following health problems:

- 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).

Contact your doctor if you experience diarrhoea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

You must tell your doctor if you think that you are (or might become) pregnant. Olmesartan /Amlodipine Mylan is not recommended in early pregnancy, and must not be taken if you are more than 3 months

pregnant, as it may cause serious harm to your baby if used at that stage (see section Pregnancy and breast-feeding).

### **Children and adolescents (under 18 years of age)**

Olmesartan /Amlodipine Mylan is not recommended for children and adolescents under the age of 18.

### **Other medicines and Olmesartan /Amlodipine Mylan**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- **Other blood pressure lowering medicines**, as the effect of Olmesartan /Amlodipine Mylan can be increased. Your doctor may need to change your dose and/or to take other precautions: If you are taking an ACE-inhibitor or aliskiren (see also information under the headings ‘Do not take Olmesartan /Amlodipine Mylan’ and ‘Warnings and precautions’).
- **Potassium supplements, salt substitutes containing potassium, ‘water tablets’** (diuretics) or **heparin** (for thinning the blood and prevention of blood clots.). Using these medicines at the same time as Olmesartan /Amlodipine Mylan may raise the levels of potassium in your blood.
- **Lithium** (a medicine used to treat mood swings and some types of depression) used at the same time as Olmesartan /Amlodipine Mylan may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- **Non-Steroidal Anti-Inflammatory Drugs** (NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Olmesartan /Amlodipine Mylan may increase the risk of kidney failure. The effect of Olmesartan /Amlodipine Mylan can be decreased by NSAIDs.
- **Colesevelam hydrochloride**, a drug that lowers the level of cholesterol in your blood, as the effect of Olmesartan /Amlodipine Mylan may be decreased. Your doctor may advise you to take Olmesartan /Amlodipine Mylan at least 4 hours before colesevelam hydrochloride.
- **Certain antacids** (indigestion or heartburn remedies), as the effect of Olmesartan /Amlodipine Mylan can be slightly decreased.
- **Medicines used for HIV/AIDS** (e.g. ritonavir, indinavir, nelfinavir) or for the treatment of fungal infections (e.g. ketoconazole, itraconazole).
- **Diltiazem, verapamil** (agents used for heart rhythm problems and high blood pressure).
- **Rifampicin** (agent used for tuberculosis or other infections).
- **Erythromycin, clarithromycin** (for infections caused by bacteria).
- **St. John’s wort** (*Hypericum perforatum*), a herbal remedy.
- **Dantrolene** (infusion for severe body temperature abnormalities).
- **Simvastatin**, an agent used to lower levels of cholesterol and fats (triglycerides) in the blood.
- **Tacrolimus, cyclosporine** (used to control your body’s immune response, enabling your body to accept the transplanted organ).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Olmesartan /Amlodipine Mylan with food and drink**

Olmesartan /Amlodipine Mylan can be taken with or without food. Swallow the tablet with some fluid (such as one glass of water). If possible, take your daily dose at the same time each day, for example at breakfast time.

Grapefruit juice and grapefruit should not be consumed by people who are taking this medicine. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient

amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of this medicine.

#### Elderly

If you are over 65 years of age, your doctor will regularly check your blood pressure at any dose increase, to make sure that your blood pressure does not become too low.

#### Black patients

As with other similar drugs the blood pressure lowering effect of this medicine can be somewhat less in black patients.

### **Pregnancy and breast-feeding**

#### Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Olmesartan /Amlodipine Mylan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Olmesartan /Amlodipine Mylan. This medicine 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.

If you become pregnant during therapy with this medicine, please inform and see your physician without delay.

#### Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Olmesartan /Amlodipine Mylan. This medicine is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

You may feel sleepy, sick or dizzy or get a headache while being treated for your high blood pressure. If this happens, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

### **Olmesartan /Amlodipine Mylan contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Olmesartan /Amlodipine Mylan**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose of Olmesartan /Amlodipine Mylan is one tablet per day.
- The tablets can be taken with or without food. Swallow the tablet with some fluid (such as a glass of water). The tablet should not be chewed. Do not take them with grapefruit juice.
- If possible, take your daily dose at the same time each day, for example at breakfast time.

**If you take more Olmesartan /Amlodipine Mylan than you should**

If you take more tablets than you should you may experience low blood pressure with symptoms such as dizziness, fast or slow heartbeat.

If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack or this leaflet with you.

**If you forget to take Olmesartan /Amlodipine Mylan**

If you forget to take a dose, take your normal dose on the following day as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Olmesartan /Amlodipine Mylan**

It is important to continue to take this medicine unless your doctor tells you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

**Although not many people may get them, the following two side effects can be serious:**

Allergic reactions, that may affect the whole body, with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Olmesartan /Amlodipine Mylan . **If this happens stop taking Olmesartan /Amlodipine Mylan and talk to your doctor immediately.**

Olmesartan /Amlodipine Mylan can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this happens stop taking Olmesartan /Amlodipine Mylan, talk to your doctor immediately and lie down flat.**

**Other possible side effects with Olmesartan /Amlodipine Mylan:****Common (may affect up to 1 in 10 people):**

- dizziness
- headache
- swelling of ankles, feet, legs, hands, or arms
- tiredness.

**Uncommon (may affect up to 1 in 100 people):**

- dizziness on standing up
- lack of energy
- tingling or numbness of hands or feet
- vertigo
- awareness of heart beat
- fast heart beat
- low blood pressure with symptoms such as dizziness, light-headedness
- difficult breathing
- cough
- nausea

- vomiting
- indigestion
- diarrhoea
- constipation
- dry mouth
- upper abdominal pain
- skin rash
- cramps
- pain in arms and legs
- back pain
- feeling more of an urge to pass urine
- sexual inactivity
- inability to get or maintain an erection
- weakness.

Some changes in blood test results have also been seen and include the following: increased as well as decreased blood potassium levels, increased blood creatinine levels, increased uric acid levels, increases in a test of liver function (gamma glutamyl transferase levels).

**Rare (may affect up to 1 in 1,000 people):**

- drug hypersensitivity
- fainting
- redness and warm feeling of the face
- red itchy bumps (hives)
- swelling of face.

**Side effects reported with use of olmesartan medoxomil or amlodipine alone, but not with Olmesartan /Amlodipine Mylan or in a higher frequency:**

**Olmesartan medoxomil**

**Common (may affect up to 1 in 10 people):**

- bronchitis
- sore throat
- runny or stuffy nose
- cough
- abdominal pain
- stomach flu
- diarrhoea
- indigestion
- nausea
- pain in the joints or bones
- back pain
- blood in the urine
- infection of the urinary tract
- chest pain
- flu-like symptoms
- pain.

Changes in blood test results as increased fat levels (hypertriglyceridaemia), blood urea or uric acid increased and increase in tests of liver and muscle function.

**Uncommon (may affect up to 1 in 100 people):**

- reduced number of a type of blood cells, known as platelets, which can result in easily bruising or prolonged bleeding time
- quick allergic reactions that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions)
- angina (pain or uncomfortable feeling in the chest, known as angina pectoris)
- itching
- eruption of the skin
- allergic skin rash
- rash with hives
- swelling of the face
- muscular pain
- feeling unwell.

**Rare (may affect up to 1 in 1,000 people):**

- swelling of the face, mouth and/or larynx (voice box)
- acute kidney failure and kidney insufficiency
- lethargy.

**Amlodipine**

**Very common (may affect more than 1 in 10 people):**

- oedema (fluid retention)

**Common (may affect up to 1 in 10 people):**

- abdominal pain
- nausea
- ankle swelling
- feeling sleepy
- redness and warm feeling of the face
- visual disturbance (including double vision and blurred vision)
- awareness of heartbeat
- diarrhoea
- constipation
- indigestion
- cramps
- weakness
- difficult breathing.

**Uncommon (may affect up to 1 in 100 people):**

- trouble sleeping
- sleep disturbances
- mood changes including feeling anxious
- depression
- irritability
- shiver

- taste changes
- fainting
- ringing in the ears (tinnitus)
- (worsening of) angina pectoris (pain or uncomfortable feeling in the chest)
- irregular heartbeat
- runny or stuffy nose
- loss of hair
- purplish spots or patches on the skin due to small haemorrhages (purpura)
- discoloration of the skin
- excessive sweating
- eruption of the skin
- itching
- red itchy bumps (hives)
- pain of joints or muscles
- problems to pass urine
- urge to pass urine at night
- increased need to urinate (pass urine)
- breast enlargement in men
- chest pain
- pain, feeling unwell
- increase or decrease in weight.

**Rare (may affect up to 1 in 1,000 people):**

- confusion

**Very rare (may affect up to 1 in 10,000 people):**

- reduction in the number of white cells in the blood, which could increase the risk of infections
- a reduction in the number of a type of blood cells known as platelets, which can result in easily bruising or prolonged bleeding time
- increase in blood glucose
- increased tightness of muscles or increased resistance to passive movement (hypertonia)
- tingling or numbness of hands or feet
- heart attack
- inflammation of blood vessels
- inflammation of the liver or the pancreas
- inflammation of stomach lining
- thickening of gums
- elevated liver enzymes
- yellowing of the skin and eyes
- increased sensitivity of the skin to light
- allergic reactions: itching, rash, swelling of the face, mouth and/or larynx (voice box) together with itching and rash, 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, sometimes life-threatening.

**Not known (frequency cannot be estimated from the available data):**

- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk
- severe skin reactions including intense skin rash (toxic epidermal necrolysis).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Olmesartan /Amlodipine Mylan**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, blister or bottle. The expiry date refers to the last day of that month.

### Blisters with desiccant

This medicine does not require any special storage conditions.

### Blisters without desiccant

Do not store above 30°C.

### Bottles

This medicine does not require any special storage conditions.

Once opened use within 100 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Olmesartan /Amlodipine Mylan contains**

The active substances are olmesartan medoxomil and amlodipine (as besilate).

Each Olmesartan /Amlodipine Mylan 20 mg/5 mg film-coated tablet contains 20 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).

Each Olmesartan /Amlodipine Mylan 40 mg/5 mg film-coated tablet contains 40 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).

Each Olmesartan /Amlodipine Mylan 40 mg/10 mg film-coated tablet contains 40 mg of olmesartan medoxomil and 10 mg amlodipine (as besilate).

The other ingredients in the core of the tablet are microcrystalline cellulose, sodium laurilsulfate, citric acid monohydrate, hydroxypropylcellulose, croscarmellose sodium, maltose, mannitol, low-substituted hydroxypropylcellulose and magnesium stearate.

The 20 mg/5 mg tablet coating contains polyvinyl alcohol, titanium dioxide (E171), macrogol and talc.

The 40 mg/5 mg tablet coating contains polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172) and iron oxide red (E172).

The 40 mg/10 mg tablet coating contains polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172) and iron oxide red (E172).

### **What Olmesartan /Amlodipine Mylan looks like and contents of the pack**

Olmesartan /Amlodipine Mylan 20 mg/5 mg: a white, round, biconvex, film-coated tablet, marked with 'M' on one side and 'OA1' on the other side.

Olmesartan /Amlodipine Mylan 40 mg/5 mg: a yellow, round, biconvex, film-coated tablet, marked with 'M' on one side and 'OA2' on the other side.

Olmesartan /Amlodipine Mylan 40 mg/10 mg: a brown, round, biconvex, film-coated tablet, marked with 'M' on one side and 'OA3' on the other side.

Blister packs of 14, 28, 56 and 98 film-coated tablets for Olmesartan /Amlodipine Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg film-coated tablets.

Plastic bottle packs of 28, 56 and 98 film-coated tablets for Olmesartan /Amlodipine Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

#### **Manufacturer**

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., Mylan utca 1, Komárom, 2900, Hungary.

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Country	Invented Name
Austria	Olmesartanmedoxomil /Amlodipin Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg Filmtabletten
Bulgaria	Olmedipin 20 mg/5 mg, 40 mg/5 mg
Germany	Olmesartanmedoxomil/Amlodipin Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg Filmtabletten
Greece	Olmesartan / Amlodipine Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg
Ireland	Olmesartan /Amlodipine Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg film-coated tablets
Italy	Olmesartan medoxomil e Almlodipina Mylan 20 mg/5 mg, 40 mg/5 mg , 40 mg/10 mg
Portugal	Olmesartan Medoxomilo / Amlodipina Mylan 20 mg/5 mg, 40 mg/5 mg, 40 mg/10 mg

**This leaflet was last revised in March 2019**