

Package Leaflet: Information for the User

Vocado 20 mg/5 mg Vocado 40 mg/5 mg Vocado 40 mg/10 mg

Film-Coated Tablets olmesartan medoxomil/amlodipine

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Vocado is and what it is used for

Vocado 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.

Vocado 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. Before you take Vocado

Do not take Vocado

- if you are allergic (hypersensitive) to olmesartan medoxomil or to amlodipine or a special group of calcium channel blockers, the dihydropyridines, or to any of the other ingredients named under section 6. If you think you may be allergic, talk to your doctor before taking Vocado.
- if you are more than 3 months pregnant. (It is also better to avoid Vocado in early pregnancy - see section "Pregnancy and breastfeeding.")
- 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).

Take special care with Vocado

Before you take these tablets, **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).

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. Vocado 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 breastfeeding").

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- **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 Vocado 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 Vocado 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 Vocado may increase the risk of kidney failure. The effect of Vocado can be decreased by NSAIDs.
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- **Other blood pressure lowering medicines**, as the effect of Vocado can be increased.
- **Certain antacids** (indigestion or heartburn remedies), as the effect of Vocado 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, erythromycin, clarithromycin** (agents used for tuberculosis or other infections).
- **St. John's wort** (*Hypericum perforatum*), a herbal remedy.
- **Dantrolene** (infusion for severe body temperature abnormalities)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Vocado with food and drink

Vocado 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 Vocado. 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 Vocado.

Children and adolescents (under 18)

Vocado is not recommended for children and adolescents under the age of 18.

Elderly patients

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 Vocado can be somewhat less in black patients.

Pregnancy and breastfeeding

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 Vocado before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Vocado. Vocado 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 Vocado, please inform and see your physician without delay.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Vocado 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.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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.

3. How to take Vocado

Always take Vocado exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual dose of Vocado 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 Vocado 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 heart beat.

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 Vocado

If you forget to take a dose, take your normal dose on the following day as usual. Do **not** take any extra tablets to make up for the missed dose.

If you stop taking Vocado

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

Please turn the page.



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

4. Possible side effects

Like all medicines, Vocado 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 Vocado. **If this happens stop taking Vocado and talk to your doctor immediately.**

Vocado 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 Vocado, talk to your doctor immediately and lie down flat.**

Other possible side effects with Vocado:

Common (affecting less than 1 in 10 patients):

Dizziness; headache; swelling of ankles, feet, legs, hands, or arms; tiredness.

Uncommon (affecting less than 1 in 100 patients):

Dizziness on standing up; lack of energy; tingling or numbness of hands or feet; vertigo; strong heart beat; fast heart beat; low blood pressure with symptoms such as dizziness, light-headedness; laboured breathing; cough; nausea; vomiting; indigestion; diarrhoea; constipation; dry mouth, upper abdominal pain; skin rash; muscle spasms; 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 (affecting less than 1 in 1,000 patients):

Drug hypersensitivity; fainting; redness and warm feeling of the face; rash with hives; swelling of face.

Side effects reported with use of olmesartan medoxomil or amlodipine alone, but not with Vocado or in a higher frequency:

Olmesartan medoxomil

Common (affecting less than 1 in 10 patients):

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 (affecting less than 1 in 100 patients):

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 (affecting less than 1 in 10,000 patients):

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

Amlodipine

Common (affecting less than 1 in 10 patients):

Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, strong heart beat.

Uncommon (affecting less than 1 in 100 patients):

Trouble sleeping; sleep disturbances; mood changes including feeling anxious; depression; irritability; shiver; taste changes; fainting; visual disturbances including double vision; ringing in the ears (tinnitus); worsening of angina pectoris (pain or uncomfortable feeling in the chest); 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; 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 (affecting less than 1 in 1,000 patients):

Confusion

Very rare (affecting less than 1 in 10,000 patients):

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 and irregular heartbeat; 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, other allergic

conditions with inflammation and peeling of the skin, sometimes life-threatening).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vocado

Keep out of the reach and sight of children.

Do not use Vocado after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Vocado contains

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

Each tablet contains 20 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).

Each tablet contains 40 mg of olmesartan medoxomil and 5 mg amlodipine (as besilate).

Each tablet contains 40 mg of olmesartan medoxomil and 10 mg amlodipine (as besilate).

Other ingredients are

Tablet core: Pregelatinised maize starch, silicified microcrystalline cellulose, croscarmellose sodium, magnesium stearate,

Tablet coat: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E171) and iron (III) oxide (E172, Vocado 40 mg/ 5 mg and 40 mg/10 mg film coated tablets only).

What Vocado looks like and contents of the pack

Vocado 20 mg/5 mg film-coated tablets are white, round with C73 on one side.

Vocado 40 mg/5 mg film-coated tablets are cream, round with C75 on one side.

Vocado 40 mg/10 mg film-coated tablets are brownish-red, round with C77 on one side.

Vocado film-coated tablets are available in packs of 14, 28, 30, 56, 90, 98 and 10 x 28, 10 x 30 film-coated tablets and in packs with perforated unit dose blisters of 10, 50 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Menarini International Operations

Luxembourg S.A.

1, Avenue de la Gare L-1611 Luxembourg

Manufacturer:

BERLIN-CHEMIE AG, Glienicker Weg

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This leaflet was last approved in

