

APPROVED PATIENT INFORMATION LEAFLET – OLMETEC® 10 and OLMETEC 20®

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. Scheduling status

S3

2. Proprietary name and dosage form

OLMETEC® 10 (10 mg Olmesartan medoxomil) Film-coated tablet

OLMETEC® 20 (20 mg Olmesartan medoxomil) Film-coated tablet

3. Composition of the medicine, that is, what this medicine contains

Each film-coated tablet contains 10 mg or 20 mg olmesartan medoxomil. It also contains microcrystalline cellulose, lactose monohydrate*, hydroxypropylcellulose, magnesium stearate, titanium dioxide (E171), talc and hypromellose.

* If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

4. Approved indication and use, that is, what this medicine is used for

HOW DO YOUR TABLETS WORK?

OLMETEC belongs to a group of medicines, which are called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

It 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 **OLMETEC** 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.

5. Instruction before taking the medicine

5.1 Ask yourself the following questions:

- Have you ever had an allergic reaction to olmesartan medoxomil or to other ingredients of **OLMETEC** tablets?
- Are you pregnant, do you think you may be pregnant, or are you planning to become pregnant?
- Are you breast-feeding?
- Do you suffer from gallstones or jaundice?
- If the answer to any of these questions is 'yes', do not take the tablets and tell your doctor or pharmacist.

5.2 What else should you know before taking the tablets?

Tell your doctor if you suffer from any of the following health problems:

- Kidney trouble or 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.

As with any medicine which reduces blood pressure, your doctor will monitor your blood pressure carefully.

5.3 Can you drive and use machinery?

It is unlikely that **OLMETEC** will affect your ability to drive or operate machinery. However, dizziness or fatigue can occasionally occur during the treatment of high blood pressure. If you notice such effects, ask your doctor for advice before driving or using machinery.

5.4 Can you take OLMETEC with other medicines?

Tell your doctor or pharmacist if you are taking any other medicines or have done so recently, even those you have bought yourself, particularly -

- if you are taking potassium supplements, a salt substitute which contains potassium, water tablets (diuretics) or heparin
- if you are taking lithium
- if you are taking Non-Steroidal Anti-Inflammatory (NSAIDs) medicines
- if you are already taking other blood pressure lowering medicines
- if you are taking certain indigestion remedies (antacids).

6. Instructions on how to take the medicine

HOW TO TAKE YOUR MEDICINE

Always take **OLMETEC** tablets exactly as instructed by your doctor. Please ask your doctor or pharmacist if you are unsure about anything.

- **How to take the tablets**

OLMETEC tablets can be taken with or without food. Swallow the tablets with a little water.

If possible, take your daily dose at the same time each day, for example at breakfast time.

It is important to continue to take **OLMETEC** tablets unless your doctor tells you to stop.

Tell your doctor if you have any worries about your treatment.

OLMETEC tablets are not recommended to be taken by children.

- **How many tablets to take - OLMETEC 10:**

The usual dose is one tablet of **OLMETEC 10** once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose to up to two tablets (20 mg olmesartan medoxomil) once a day or prescribe additional medicines.

- **How many tablets to take - OLMETEC 20:**

The usual dose is one tablet of **OLMETEC 20** once a day. However, if your blood pressure is not controlled, your doctor may decide to prescribe additional medicines.

- **What if you take too many tablets or miss a dose?**

If you have taken more tablets than you should or if a child has swallowed the tablets, contact your doctor or nearest hospital emergency department immediately and take your medicine pack with you.

If you forget 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.

7. **Side effects**

WHAT PROBLEMS MAY THE TABLETS CAUSE?

OLMETEC is suitable for most people. However, like all medicines, the tablets can have side effects. If they do occur, they are often mild and do not require treatment to be stopped.

Common side effects include the following:

Dizziness, feeling sick, indigestion, diarrhoea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain in the chest, back, bones or joints, infection of the urinary tract, swollen ankles, blood in the urine.

Some changes in blood test results have also been seen and include the following:

Increased fat levels (hypertriglyceridaemia), increased uric acid levels (hyperuricaemia), increases in tests of liver and muscle function.

Less common side effects include the following:

Vertigo, skin rash, angina.

Rare side effects:

Feeling light-headed, faint or dizzy. If this happens stop taking **OLMETEC** and contact your doctor immediately.

Rarely, blood test results have shown increased potassium levels (hyperkalaemia).

Very rarely:

Swelling of the tissue of the face, mouth and/or larynx (voice box) may occur during treatment with this medicine. If this happens stop taking **OLMETEC** and contact your doctor immediately. Tell your doctor or pharmacist as soon as possible if you notice any side effects, even if they are not listed in this leaflet.

8. Storage and disposal information

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

Store at temperatures below 30 °C.

9. Presentation

Olmotec® 10 and Olmetec® 20:

Aluminium/aluminium laminated blister packs of 14, 28, 56, 98 film-coated tablets or packs of 10 x 28 film-coated tablets.

Packs with perforated unit dose Aluminium/aluminium laminated blisters of 10, 50 and 500 film-coated tablets.

10. Identification

Olmotec® 10: White, circular, film-coated tablets with C13 embossed on one side.

Olmotec® 20: White, circular, film-coated tablets with C14 embossed on one side.

11. Registration numbers

Olmotec® 10: A40/7.1.3/0403

Olmotec® 20: A40/7.1.3/0404

12. Name and business address of the holder of the certificate of registration

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13. Date of publication of the Patient Information Leaflet: 09 October 2009