PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

OLMETEC 10 mg film-coated tablets

OLMETEC 20 mg film-coated tablets

OLMETEC 40 mg film-coated tablets

Olmesartan medoxomil

Contains sugar:

OLMETEC 10 contains 61,6 mg lactose monohydrate per film-coated tablet.

OLMETEC 20 contains 123,2 mg lactose monohydrate per film-coated tablet.

OLMETEC 40 contains 246,4 mg lactose monohydrate per film-coated tablet.

Read all of this leaflet carefully before you start taking or giving OLMETEC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- OLMETEC has been prescribed for you or a child in your care personally and you should not share OLMETEC with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OLMETEC is and what it is used for

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

OLMETEC is used for the treatment of high blood pressure (also known as hypertension) in adults and in children and adolescents aged 6 to less than 18 years.

2. What you need to know before you take or give OLMETEC

Do not take or give OLMETEC:

- If you or a child in your care is allergic to olmesartan medoxomil or any of the other ingredients of OLMETEC listed in section 6 of this leaflet.
- If you are pregnant.
- If you or a child in your care has problems with drainage of the bile from the gallbladder (biliary obstruction, e.g. gallstones).
- If you or a child in your care has diabetes or impaired kidney function and you or a child in your care are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions:

Take special care with OLMETEC:

- If you or a child in your care suffers from severe vomiting, diarrhoea, are being treated with high doses of water tablets (diuretics) or if you or a child in your care are on a low salt diet.
- If you or a child in your care has heart failure or problems with your heart valves or heart muscle.
- If you or a child in your care has kidney or liver problems.
- If you or a child in your care has increased levels of potassium in your blood.
- If you or a child in your care has problems with your adrenal glands.

Contact your doctor if you or a child in your care experiences diarrhoea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate the symptoms and decide on how to continue with the 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 or a child in your care's blood pressure carefully.

You must tell your doctor if you think you are (or might become) pregnant. OLMETEC 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 Pregnancy and breastfeeding section).

Black patients:

The blood pressure lowering effect of OLMETEC is somewhat less in black patients.

Children and adolescents:

OLMETEC has been studied in children and adolescents. For more information, talk to your doctor. OLMETEC is not recommended for children from 1 year to less than 6 years and should not be used in children under the age of 1 year as no experience is available.

Other medicines and OLMETEC:

Always tell your health care provider if you are taking or giving a child in your care any other medicines. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you or a child in your care is currently taking:

- Other blood pressure lowering medicines, as the effect of OLMETEC can be increased.
- An ACE inhibitor or aliskiren (used to treat high blood pressure).
- Potassium supplements, a salt substitute which contains potassium, water tablets (diuretics)

or heparin (for blood thinning). Using these medicines at the same time as OLMETEC may raise blood potassium levels.

- Non-steroidal anti-inflammatory drugs (NSAIDs) (medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis). Using these medicines at the same time as OLMETEC may increase the risk of kidney failure and the effect of OLMETEC can be decreased by NSAIDs.
- Colesevelam hydrochloride (a medicine that lowers blood cholesterol levels), as the effect of OLMETEC may be decreased. Your doctor may advise you to take or give OLMETEC at least 4 hours before colesevelam hydrochloride.
- Certain antacids (indigestion remedies), as the effect of OLMETEC can be slightly decreased.
- Lithium (a medicine used to treat mood swings and depression). Using lithium at the same time as OLMETEC may increase the toxicity of lithium. If you or a child in your care has to take lithium, your doctor will measure your or your child's lithium blood levels.

OLMETEC with food:

There are no known interactions between OLMETEC and food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking OLMETEC.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking OLMETEC before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of OLMETEC. OLMETEC is not recommended in early pregnancy, and must not be taken when you are more than 3 months pregnant (see "Do not take OLMETEC"), as it may cause serious harm to your baby if used after

the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. OLMETEC is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines:

It is not always possible to predict to what extent OLMETEC may interfere with your daily activities. OLMETEC can cause side effects such as sleepiness and dizziness. If this happens, do not drive a vehicle, use machines or do anything that requires mental alertness until the symptoms wear off. You should ensure that you do not engage in the above activities until you are aware of the measure to which OLMETEC affects you.

OLMETEC contains lactose:

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

3. How to take or give OLMETEC

Do not share medicines prescribed for you or a child in your care with any other person.
Always take or give OLMETEC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is one 10 mg tablet once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose up to 20 or 40 mg once a day, or prescribe additional medicines.

If you have mild to moderate kidney disease, your dose will not be higher than 20 mg once a day.

Children and adolescents from 6 to less than 18 years of age

The recommended starting dose is 10 mg once daily. If a child in your care's blood pressure is not adequately controlled, the doctor may decide to change the dose up to 20 or 40 mg once a day. In children who weigh less than 35 kg, the dose will not be higher than 20 mg once a day.

Your doctor will tell you how long you or a child in your care's treatment with OLMETEC will last.
Do not stop your or a child in your care's treatment without discussing it with you doctor, first.
If you have the impression that the effect of OLMETEC is too strong or too weak, tell your doctor or pharmacist.

If you take or give more OLMETEC than you should:

In the event of overdosage, or if a child accidentally swallows some, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you or a child in your care has taken.

If you forget to take or give OLMETEC:

If you or a child in your care have missed a dose of OLMETEC, take or give the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take or give OLMETEC at the next regularly scheduled time.
Do not take or give a double dose to make up for the forgotten individual doses.

If you stop taking or giving OLMETEC:

Do not stop taking or giving OLMETEC unless your doctor tells you to.

4. Possible side effects

OLMETEC can have side effects.

Not all side effects reported for OLMETEC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OLMETEC, please consult your doctor, pharmacist or health care provider for advice.

If any of the following happens to you or a child in your care, stop taking or giving OLMETEC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash, hives or itching
- fainting.

These are all very serious side effects. If you or a child in your care have them, it may be because of a serious reaction to OLMETEC. You or a child in your care may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- angina pectoris (a pain or uncomfortable feeling in your chest, often spreading to your arms or neck and sometimes to your shoulders and back)
- too high levels of potassium when blood tests are done (palpitations or irregular heart rate, trouble breathing, tiredness or weakness)
- severe, chronic diarrhoea with a substantial decrease in body mass, as well as abdominal pain, fatigue, bloating, nausea (feeling sick), vomiting (being sick), and anaemia (sprue-like enteropathy)
- blood in your urine
- kidney failure (passing little or no urine, drowsiness, breathlessness)
- chest pain.

These are all serious side effects. You or a child in your care may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness, headaches
- bronchitis (coughing mucus, chest discomfort, fever, chills)
- sore throat, cough, runny or blocked nose
- inflammation of your stomach or intestines (nausea, vomiting)
- diarrhoea, abdominal pain, indigestion
- pain, back pain, bone or joint pain
- urinary tract infection (strong and frequent urge to urinate, pain and burning sensation when urinating, cloudy, bloody or strong-smelling urine, abdominal pain)
- flu-like symptoms, tiredness
- increased urea, liver enzymes or creatinine phosphokinase levels when blood tests are done.

Less frequent side effects:

- bleeding or bruising more easily than normal
- increased fat levels (hypertriglyceridaemia) or increased uric acid levels (hyperuricaemia) when blood tests are done
- vertigo (sensation of spinning or swaying)
- low blood pressure
- muscle pain or spasm
- impaired kidney function
- weakness, feeling unwell
- lack of interest and energy
- increased creatinine levels when blood tests are done.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of OLMETEC.

5. How to store OLMETEC

- Store at or below 30 °C.
- Keep the blister strip in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OLMETEC contains

The active substance in OLMETEC is olmesartan medoxomil.

OLMETEC 10 contains 10 mg olmesartan medoxomil.

OLMETEC 20 contains 20 mg olmesartan medoxomil.

OLMETEC 40 contains 40 mg olmesartan medoxomil.

The other ingredients are:

Tablet core

Hydroxypropyl cellulose

Lactose monohydrate

Low substituted hydroxypropyl cellulose

Magnesium stearate

Microcrystalline cellulose.

Tablet coating

Hypromellose

Talc

Titanium dioxide (E171).

What OLMETEC looks like and contents of the pack

OLMETEC 10: White circular film-coated tablets with characteristic odour approximately 6,5 mm in diameter, with C13 debossed on one side.

OLMETEC 20: White circular film-coated tablets with characteristic odour approximately 8,5 mm in diameter, with C14 debossed on one side.

OLMETEC 40: White oval film-coated tablets with characteristic odour approximately 15 x 7 mm in size, with C15 debossed on one side.

Aluminium/aluminium blister strips in a carton containing 10, 14, 28, 30, 50, 56, 84, 90, 98, 280 or 500 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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OLMETEC 10: A40/7.1.3/0403

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OLMETEC 40: 40/7.1.3/0405

Access to corresponding Professional Information

Request via the email address: info@menarini.co.za