PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

OLMETEC PLUS 20/12,5 film-coated tablets

OLMETEC PLUS 20/25 film-coated tablets

Olmesartan medoxomil and hydrochlorothiazide

Contains sugar (lactose monohydrate):

Each OLMETEC PLUS 20/12,5 film-coated tablet contains 110,70 mg sugar (lactose monohydrate)

Each OLMETEC PLUS 20/25 film-coated tablet contains 98,20 mg sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking OLMETEC PLUS:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OLMETEC PLUS 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.

What is in this leaflet

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

1. What OLMETEC PLUS is and what it is used for

OLMETEC PLUS contains two active substances, olmesartan medoxomil and hydrochlorothiazide.

Olmesartan medoxomil belongs to a group of medicines called angiotensin II-receptor antagonists. It lowers blood pressure by relaxing the blood vessels.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics ("water tablets"). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

OLMETEC PLUS is used for treating high blood pressure in patients whose blood pressure is not effectively controlled on olmesartan medoxomil alone.

2. What you need to know before you take OLMETEC PLUS

Do not take OLMETEC PLUS:

- If you are hypersensitive (allergic) to olmesartan medoxomil or hydrochlorothiazide or any of the other ingredients of OLMETEC PLUS (listed in section 6).
- If you are pregnant or you are breastfeeding your baby (see section 2 "Pregnancy and breastfeeding").
- If you have a history of swelling related to previous therapy with ACE inhibitors or angiotensin receptor blockers (ARBs) you must never again be given these medicines.
- If your heart muscle becomes thickened and stiff, making it harder for your heart to pump blood out of your heart and around your body [hypertrophic obstructive cardiomyopathy (HOCM)].
- If you have a problem with your kidneys, particularly if it is a blockage of the blood vessel which supplies oxygen-rich blood to your kidneys (renal artery stenosis), and/or you have a single kidney.
- If you have narrowing or blockage of your heart valves (aortic stenosis).
- If you are taking "water pills" (diuretics) that cause your body to retain potassium (such as spironolactone, triamterene or amiloride).
- If you suffer from porphyria.
- If you are taking medication which contains aliskiren, used for treatment of high blood pressure.
- If you are taking lithium, used for treatment of mental health problems, such as bipolar

disorder, depression and schizophrenia (see section 2 “Other medicines and OLMETEC PLUS”).

- If you suffer from severe kidney problems or the inability to pass urine normally.
- If you suffer from severe liver problems or yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction, e.g. gallstones).
- If you have low potassium, low sodium, high calcium or high levels of uric acid levels in the blood that do not get better when treated.
- If you have previously had or currently have cancer of the skin and/or lip.

If you think any of these apply to you, or you are unsure, do not take the tablets. Talk to your doctor first and follow the advice given.

Warnings and precautions

Take special care with OLMETEC PLUS:

- If you are taking ACE inhibitors, angiotensin II receptor blockers (ARBs) or aliskiren (used to treat high blood pressure) as it may increase the risk of low blood pressure, increased blood potassium levels and decreased kidney function.
- If you are dehydrated or have diarrhoea or vomiting, then your water and sodium levels need to be corrected before you take OLMETEC PLUS.
- If you have mild to moderate kidney problems, ensure that you regularly monitor your potassium, creatinine and uric acid levels.
- If you suffer from high cholesterol, then monitor your cholesterol levels regularly while on treatment with OLMETEC PLUS.
- If you are taking medication used to treat diabetes, (either oral or injection), please consult your doctor as your diabetic medication dose may need to be adjusted.
- If you experience persistent dryness of the mouth and thirst, weakness, tiredness, drowsiness, restlessness, muscle pain or cramps, this can be the result of salt (such as potassium, sodium and calcium) and water imbalances caused by OLMETEC PLUS. Your doctor will monitor the amount of salts in your blood at regular intervals.

- If you are taking potassium supplements or salt substitutes or other medicines that can increase your blood potassium levels (e.g. blood thinning medicines such as heparin) or “water pills” (diuretics) that make your body to retain potassium, the amount of potassium in your blood can increase and result in a condition called hyperkalaemia (see section 2 “Taking other medicines with OLMETEC PLUS”).
- If you develop severe and persistent diarrhoea that causes substantial weight loss (see section 4 “Possible side effects”). Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.
- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking OLMETEC PLUS. This can lead to permanent vision impairment, if not treated.
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide in OLMETEC PLUS, 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 OLMETEC PLUS.
- If you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking OLMETEC PLUS, seek medical attention immediately.
- If you are going for an anti-doping test, the hydrochlorothiazide contained in OLMETEC PLUS may produce a positive result.
- If you have ischaemic heart disease (a condition where your heart is not getting enough blood flow and oxygen) as a result of the thickening and hardening of the walls of the arteries (arteriosclerosis), taking OLMETEC PLUS can result in excessive lowering of blood pressure.
- 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 monitor your blood pressure regularly while you are taking OLMETEC PLUS.

- If you suffer from systemic lupus erythematosus (joint pain and stiffness, often accompanied by swelling and redness, skin rash on the face that extends over the bridge of the nose and cheeks, fever, extreme fatigue, loss of appetite, nausea, and weight loss), the use of OLMETEC PLUS can worsen the symptoms.

Children and adolescents

OLMETEC PLUS is not recommended for children and adolescents under the age of 18 years.

Other medicines and OLMETEC PLUS

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

- Do not take any medicine containing aliskiren (used to treat high blood pressure if you are on treatment with OLMETEC PLUS.
- Do not take any medicine containing lithium if you are on treatment with OLMETEC PLUS as it may increase the toxicity of lithium.
- OLMETEC PLUS can enhance the effect of baclofen or tubocurarine (a medicine used to relax muscles or spasms).
- Combination of OLMETEC PLUS with non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, aspirin, celecoxib or etoricoxib (medicines used to relieve pain and inflammation may enhance the blood pressure lowering effect of OLMETEC PLUS as well as its side effects on your kidney function especially if you are an elderly person. Your doctor may monitor your kidney function and blood pressure at regular intervals.
- If you have kidney problems and you are on long term anti-inflammatory treatment, please consult your doctor before starting treatment on OLMETEC PLUS.
- If you are taking ACE inhibitors or angiotensin II receptor blockers (ARBs) as it may increase the risk of low blood pressure, increased blood potassium levels and decreased kidney function if taken together with OLMETEC PLUS.

- OLMETEC PLUS can enhance the effect of amifostine, a medicine used to protect your kidneys against the harmful effects of chemotherapy (cancer treatment).
- If you are taking any other medication used to lower your blood pressure, please tell your doctor as taking OLMETEC PLUS in combination with this treatment may cause a significant reduction in your blood pressure.
- If you are taking sleeping tablets, sedatives and anti-depressant medicines, please contact your doctor as using these medicines together with OLMETEC PLUS may cause a sudden drop in blood pressure when standing up.
- Potassium-sparring diuretics (“water pills”) such as spironolactone, triamterene, amiloride used to treat high blood pressure or potassium supplements or salt substitutes containing potassium or medicines can increase your blood potassium levels (e.g. blood thinner such as heparin). You should not take these medicines together with OLMETEC PLUS (see section 2, “Do not take OLMETEC PLUS”).
- Colesevelam hydrochloride, a medicine that lowers the level of cholesterol in your blood, as the effect of OLMETEC PLUS may be decreased. Your doctor may advise you to take OLMETEC PLUS at least 4 hours before colesevelam hydrochloride.
- If you are taking certain antacids (indigestion or heartburn remedies) that contain aluminium magnesium hydroxide, please consult your doctor as the effect of OLMETEC PLUS can be decreased.
- OLMETEC PLUS had no significant effect on the absorption of warfarin and digoxin.
- As the diuretic (“water pill”) effect of OLMETEC PLUS can cause potassium-depletion, it should not be taken together with medicines such as laxatives, corticosteroids, kaliuretic diuretics, aspirin and penicillin G sodium (also called benzylpenicillin sodium, an antibiotic) that cause loss of potassium from your body. The potassium lowering effect of OLMETEC PLUS can also potentiate the side effects of digoxin (medicine used to treat heart failure).
- If you are taking calcium supplements, please consult your doctor as combination with OLMETEC PLUS can increase the amount of calcium in your blood. Your doctor will need to monitor the level of calcium and may also need to adjust the dose.

- Use of cholestyramine or colestipol resins (medicines used to reduce cholesterol levels in the blood) may affect absorption of OLMETEC PLUS.
- Anticholinergic medicines, such as atropine and biperiden.
- If you are taking medication used to treat diabetes (such as metformin or insulin), please consult your doctor as your diabetic medication dose may need to be adjusted.
- Beta-blockers and diazoxide, medicines used to treat high blood pressure or low blood sugar, respectively, as OLMETEC PLUS can enhance their blood-sugar-increasing effect.
- If you are taking medication used to treat gout (probenecid, sulfinpyrazone and allopurinol), please consult your doctor as your gout medication dose may have to be adjusted as OLMETEC PLUS may increase the level of serum uric acid in your blood.

Please tell your doctor if you are taking any medication containing the following as your potassium levels will need to be monitored:

- Medicines used to treat irregular heartbeat (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide).
- Digoxin.
- Some antipsychotics, medicines used to treat psychosis and other mental and emotional conditions (e.g. thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopride, amisulpride, tiapride, pimozide, haloperidol, droperidol).
- Bepridil, used to treat high blood pressure and angina (chest pains).
- Cisapride, used to treat the symptoms such as heartburn.
- Diphemanil, used to decrease secretion of stomach acids as well as saliva and sweat thereby decreasing the amounts.
- Erythromycin and sparfloxacin, medicines used to fight bacteria in the body (antibiotic).
- Halofantrin, used to treat malaria.
- Mizolastine, an antihistamine used to treat allergic conditions such as hay fever.
- Pentamidine, an anti-infective medicine used to prevent pneumonia.
- Vincamine, used to enhance memory.

Also tell your doctor if you are taking any medication that contains the following, as OLMETEC PLUS can potentiate their effects:

- Salicylates (e.g aspirin), a medicine used to relieve pain and inflammation.
- Methyldopa, a medicine used to treat high blood pressure or Parkinson's disease.
- Amantadine, an anti-viral medicine or medicine used for Parkinson's.
- Medicines such as ciclosporin, cyclophosphamide and methotrexate used for treatment of cancer.
- Tetracycline, an antibiotic used to fight bacteria in the body.
- Norepinephrine (noradrenaline) used for treatment of low blood pressure and slow heart rate.

OLMETEC PLUS with food or drink

Do not consume alcohol when you are on treatment with OLMETEC PLUS.

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 for advice before taking OLMETEC PLUS.

Do not use OLMETEC PLUS if you are pregnant. OLMETEC PLUS can cause serious harm or death to your unborn baby if you take it while you are pregnant.

Mothers on OLMETEC PLUS should not breastfeed their babies.

Driving and using machines

The effect of OLMETEC PLUS on the ability to drive and use machines has not been specifically studied. However, it should be borne in mind that dizziness or fatigue may occur when taking OLMETEC PLUS. Do not drive or operate any tools or machines until you know **how** OLMETEC

PLUS affects you.

OLMETEC PLUS contains lactose monohydrate

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

3. How to take OLMETEC PLUS

Do not share medicines prescribed for you with any other person.

Always take OLMETEC PLUS exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: OLMETEC PLUS is taken once daily, with or without food.

A maximum dose of OLMETEC PLUS 20/25 should not be exceeded.

Elderly: In elderly patients the same dosage of the combination is recommended as for adults.

Swallow the tablet with water. If possible, you should take your dose at the same time each day, for example at breakfast time.

If you have the impression that the effect of OLMETEC PLUS is too strong or too weak, tell your doctor or pharmacist.

If you take more OLMETEC PLUS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take more tablets than you should, or if a child accidentally swallows one or more, go to your doctor or nearest accident and emergency department immediately and take your medicine pack

with you.

If you forget to take OLMETEC PLUS

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.

Do not take a double dose of OLMETEC PLUS to make up for forgotten individual doses.

If you stop taking OLMETEC PLUS

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

4. Possible side effects

OLMETEC PLUS can have side effects.

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

If any of the following happens, stop using OLMETEC PLUS 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 or itching.
- Fainting.
- Toxic epidermal necrolysis (TEN), a life-threatening skin condition where top layer of the skin peels off, usually the mucous membranes (eye, mouth, vagina) are affected.

These are all very serious side effects. If you have them, you may have had a serious reaction to OLMETEC PLUS. You 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:

- Skin and lip cancer (non-melanoma skin cancer); the appearance of a lump or discoloured patch on the skin that persists after a few weeks.
- Yellowing of the skin and eyes, also called jaundice.
- 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.
- Angina (pain or uncomfortable feeling in the chest, known as angina pectoris).
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Blood clots (thrombosis or embolism).
- Severe shortness of breath, difficulty breathing, infection that inflames lungs (pneumonia), infection of the lungs or fluid build-up in the lungs (acute respiratory distress syndrome).
- Convulsions (also known as fits or seizures).
- Signs of frequent infections such as fever or sore throat, coughing, stuffy and runny nose, painful urination or burning urine as a sign of urinary tract infection, infection of salivary glands with mumps-like symptoms (e.g. swollen face, abnormal taste, dry mouth, pain in the mouth or face).
- Kidney failure or poor functioning of the kidneys.
- Reduction of amount of urine.
- Red discolouration of urine or presence of blood in the urine.
- Severe and chronic diarrhoea with substantial weight loss, as well as abdominal pain, fatigue, bloating, nausea, vomiting, and anemia (sprue-like enteropathy) (see section 4.4).

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Rise in blood fat levels, rise in blood urea or uric acid, rise in creatinine.
- Electrolyte imbalances (decrease in magnesium and sodium levels).
- Rise in blood sugar, rise in blood calcium levels, increase of serum amylase (hyperamylasaemia).

- Dizziness or light-headedness.
- Headache.
- Feeling confused.
- Vertigo (a sensation of feeling off balance or dizzy).
- Cough or coughing up thickened mucus and shortness of breath (bronchitis).
- Sore throat (pharyngitis) or stuffy nose (rhinitis).
- Abdominal cramps or stomach pains.
- Diarrhoea or nausea.
- Vomiting.
- Upset stomach or accumulation of gas (meteorism).
- Constipation.
- Bloatedness or indigestion.
- Flatulence.
- Stomach flu (gastroenteritis).
- Pain in the joints (arthritis) or bones, back pain.
- Haematuria (blood in the urine).
- Urinary tract infection.
- Chest pain.
- Cold or flu symptoms.
- Pain.
- Tiredness.
- Decreased muscle strength.
- Increase in levels of liver function.
- Abnormal kidney function tests.

Less frequent side effects:

- Changes to your cell counts (decreased number of white blood cells, decreased number of blood platelets, anaemia, bone marrow damage).

- Anorexia, a condition where you may restrict your eating habits due to fear of gaining weight.
- Decrease in blood chloride.
- Restlessness, feeling ‘down’ or depressed, problems sleeping.
- Feeling un-interested (apathy).
- Drowsiness.
- Disturbances in consciousness, including loss of consciousness.
- Loss of appetite.
- Partial loss of voluntary movement.
- Objects you look at appearing yellow, transient blurred vision, dry eyes, reduced tears.
- Having colour vision problems.
- Low blood pressure or experiencing low blood pressure when you suddenly stand up after sitting or lying down (orthostatic hypotension).
- Inflammation of the blood vessels (vasculitis).
- Inflammation of the pancreas.
- Infection in the gall bladder.
- Skin reaction induced by sunlight.
- Muscle spasm or pain.
- Muscle cramps, pain in limbs or joint stiffness.
- A feeling of numbness, tingling or burning.
- Erectile or sexual dysfunction.
- Fever.
- Feeling weak or ill (malaise).
- Increase or decrease in blood potassium levels.
- Rise in blood urea nitrogen, decrease in haemoglobin and haematocrit values.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OLMETEC PLUS.

5. How to store OLMETEC PLUS

Store at or below 30 ºC.

Keep blister in carton until required for use.

Do not use after the expiry date printed on the outer container and blister.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What OLMETEC PLUS contains

The active substances are olmesartan medoxomil and hydrochlorothiazide.

Each OLMETEC PLUS 20/12,5 film-coated tablet contains 20 mg olmesartan medoxomil and 12, 5 mg hydrochlorothiazide**.**

Each OLMETEC PLUS 20/25 film-coated tablet contains 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide.

Tablet core

Hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose.

Film coat

OLMETEC PLUS 20/12,5: Opadry O2A22352

OLMETEC PLUS 20/25: Opadry O2A24576

[Opadry O2A22352 & Opadry O2A24576 contains hypromellose, talc, titanium dioxide (E171), iron (III) oxide yellow (E172), iron (III) oxide red (E172)].

What OLMETEC PLUS looks like and contents of the pack

OLMETEC PLUS 20/12,5: Reddish-yellow, round, film-coated tablet with C22 debossed on one side.

OLMETEC PLUS 20/25: Pinkish, round, film-coated tablet with C24 debossed on one side.

Blister packs comprised of aluminium / aluminium (polyamide/polyvinyl chloride) laminated foil**.**

Pack size: 14, 28, 30, 56, 84, 90, 98 film-coated tablets or packs of 10 x 28 film-coated tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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