SCHEDULING STATUS

S3

ADCO TELMISARTAN 20, 20 mg tablets
ADCO TELMISARTAN 40, 40 mg tablets
ADCO TELMISARTAN 80, 80 mg tablets
Telmisartan

Contains sugar (mannitol (E 421)):
ADCO TELMISARTAN 20: 81,9 mg per tablet
ADCO TELMISARTAN 40: 163,8 mg per tablet
ADCO TELMISARTAN 80: 327,7 mg per tablet

Read all of this leaflet carefully before you start taking ADCO TELMISARTAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADCO TELMISARTAN 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 ADCO TELMISARTAN is and what it is used for

ADCO TELMISARTAN belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a hormone produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. ADCO TELMISARTAN blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

ADCO TELMISARTAN is used to treat essential hypertension (high blood pressure).
ADCO TELMISARTAN can also be used to reduce cardiovascular events and death in patients who are 55 years or older who are at high risk of cardiovascular disease. The benefit of treatment

for these patients is evident after at least 6 months of continued treatment.

2. What you need to know before you take ADCO TELMISARTAN

Do not take ADCO TELMISARTAN:

- If you are hypersensitive (allergic) to telmisartan or any of the other ingredients of ADCO TELMISARTAN (listed in section 6).
- If you are pregnant or breastfeeding your baby (see section “Pregnancy, breastfeeding and fertility”).
- If you have had angioedema (swelling of your face, lips, mouth, tongue or throat, with or without difficulty in swallowing or breathing) while taking an angiotensin-converting enzyme inhibitor (ACE inhibitor) or an angiotensin receptor blocker, such as ADCO TELMISARTAN.
- If you have a disorder that results in regular outbreaks of severe swelling (hereditary angioedema) or swelling that occurs for no reason at all (idiopathic angioedema).
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of your heart) and the aorta (the main artery leading away from your heart).
- If you have hypertrophic obstructive cardiomyopathy, a serious heart disorder where the muscles of the heart are thickened, interfering with normal blood flow.
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney.
- If you are taking diuretics (water tablets) such as spironolactone, triamterene or amiloride, that cause your body to retain potassium.
- If you have severe kidney disease.
- If you have severe liver problems such as problems with the drainage of the bile from the liver and gall bladder, or any other severe liver disease.
- If you have a condition called porphyria (a metabolic disorder).
- If you are taking lithium (used as treatment for mood disorders).
- If you are using medicines containing aliskiren (used to treat high blood pressure).
- Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Warnings and precautions

Take special care with ADCO TELMISARTAN:

- If you are pregnant or trying to fall pregnant. You should stop treatment immediately and use a different medicine to control your high blood pressure.
- If you are also taking any of the following medicines to treat your high blood pressure:
    - an ACE inhibitor (for example lisinopril) or aliskiren. When these medicines are used together, it may increase the risk for you to have very low blood pressure and can increase the amount of potassium in your blood. It can also decrease

your kidney function.

- If you are also taking a type of antibiotic known as fluoroquinolones (ciprofloxacin, moxifloxacin, levofloxacin). Your doctor should assess your kidney function before you use these antibiotics with ADCO TELMISARTAN.

Before taking ADCO TELMISARTAN tell your doctor, pharmacist or other health care professional if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both of your kidneys).
- Liver disease.
- Heart problems.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood, or if you are taking medicines that may increase the potassium levels in your blood such as potassium-sparing diuretics (water tablets), potassium supplements, salt substitutes containing potassium or other medicines that may increase the potassium level (for instance heparin).
  Your doctor will monitor your potassium levels while you are taking ADCO TELMISARTAN.
- Diabetes.
- ADCO TELMISARTAN may be less effective in lowering the blood pressure in black patients.

Children and adolescents

ADCO TELMISARTAN is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

Other medicines and ADCO TELMISARTAN

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

Tell your doctor or pharmacist if you are currently using:

- Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) or renin inhibitors, such as aliskiren (used to treat high blood pressure). The combined use of these medicines may lead to a higher frequency of side effects such as low blood pressure, high levels of potassium in your blood and decreased kidney function.
- Any other medicines that lower blood pressure.
- Medicine containing lithium, used to treat some types of mood disorders. The amount of

lithium in your blood may increase to toxic levels when taken with ADCO TELMISARTAN.
- Digoxin, used to treat heart problems.
- Nonsteroidal anti-inflammatory medicines (NSAIDs), such as aspirin, diclofenac and ibuprofen. You have an increased risk to develop kidney damage especially if you are dehydrated when taking with ADCO TELMISARTAN.
- Spironolactone, eplerenone, triamterene, amiloride. The amount of potassium in your blood may increase when taken with ADCO TELMISARTAN.
  Combination treatment with potassium-sparing diuretics is contraindicated (see section “Do not take ADCO TELMISARTAN”).
- Potassium supplements, salt substitutes containing potassium and other medicines that may increase potassium levels. The amount of potassium in your blood may increase when taken with ADCO TELMISARTAN.
- Other medicines that may lead to increased potassium levels in your blood when taken with ADCO TELMISARTAN are ACE inhibitors, other angiotensin II receptor antagonists, NSAIDs, heparin, immunosuppressives (such as cyclosporin and tacrolimus) and trimethoprim.
- Baclofen (used to treat muscle stiffness). This medicine may increase the blood pressure lowering effect of ADCO TELMISARTAN.
- Amifostine (used after initial treatment for cancer, to suppress secondary tumour formation). This medicine may increase the blood pressure lowering effect of ADCO TELMISARTAN.
- Barbiturates (used to treat sleeping disorders).
- Narcotics (used to treat mood and behaviour disorders).
- Antidepressant medicine (used to treat depression).
- Alcohol.
- Corticosteroids (cortisone-like medicines used to treat inflammation). Treatment with corticosteroids and ADCO TELMISARTAN may lead to a decrease of the blood pressure lowering effect of ADCO TELMISARTAN.
- Fluoroquinolone antibiotics (antibiotics to treat your infection). When taken with ADCO TELMISARTAN, it may trigger kidney injury.
- When taking ADCO TELMISARTAN just after you have taken high doses of furosemide and/or hydrochlorothiazide may lead to volume depletion and lower than usual blood pressure.

ADCO TELMISARTAN may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

ADCO TELMISARTAN with food and drink

You can take ADCO TELMISARTAN with or without food.

Pregnancy, breastfeeding and fertility

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 this medicine.

Do not use ADCO TELMISARTAN if you are pregnant or breastfeeding.

When pregnancy is planned or confirmed, ADCO TELMISARTAN should be stopped immediately.

When you take ADCO TELMISARTAN while you are pregnant, it can cause harm to your unborn baby.

Women of childbearing age should use adequate contraception.

No effects of telmisartan, as in ADCO TELMISARTAN, on male and female fertility were observed in reported studies.

Driving and using machines

ADCO TELMISARTAN may cause dizziness or drowsiness, thereby impairing your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how ADCO TELMISARTAN will affect you.

ADCO TELMISARTAN contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dosage unit (5 ml), that is to say essentially 'sodium-free'.

3. How to take ADCO TELMISARTAN

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

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

Treatment for high blood pressure

The usual dose of ADCO TELMISARTAN for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. Your doctor may recommend a lower dose of one 20 mg tablet daily. Your doctor may also increase your dose to one 80 mg tablet per day if your target blood pressure is not achieved. Try to take the tablet at the same time each day. The tablets should be swallowed with some water.

ADCO TELMISARTAN may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide (12,5 mg), which has been shown to have an additive blood pressure lowering effect with ADCO TELMISARTAN.

If your doctor increases your dose, you must bear in mind that the maximum blood pressure

lowering effect is generally achieved four to eight weeks after the start of treatment.

If you have mild to moderate liver disease, you should not take more than one 40 mg tablet per day.

To reduce cardiovascular events and death in patients who are 55 years or older who are at high risk of cardiovascular disease
The usual dose is one 80 mg tablet daily.
When ADCO TELMISARTAN therapy is started for the reduction of cardiovascular events and death, your doctor should monitor your blood pressure and if appropriate, adjust your blood pressure lowering medicines.
The benefit of treatment is evident only after 6 months of continued treatment.

Your doctor will tell you how long your treatment with ADCO TELMISARTAN will last. It is important that you take ADCO TELMISARTAN every day until your doctor tells you otherwise. Do not stop treatment without consulting your health care provider.
If you have the impression that the effect of ADCO TELMISARTAN is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO TELMISARTAN than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining ADCO TELMISARTAN with you so the doctor will know what you have taken.
If you take more ADCO TELMISARTAN than you should, you may experience very low blood pressure (you may feel dizzy or you may faint) and an increased heartbeat. In some instances, you may also experience a very slow heartbeat.
Treatment of overdose is symptomatic and supportive. Serum electrolytes and creatinine concentrations should be monitored frequently. Activated charcoal may be useful in the treatment of overdosage. If you get very low blood pressure, you should be placed on your back and salt and volume replacement given as quick as possible.

If you forget to take ADCO TELMISARTAN
If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ADCO TELMISARTAN at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking ADCO TELMISARTAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADCO TELMISARTAN. 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:
Side effects occurring less frequently:

- Fast heartbeat (tachycardia), slow heartbeat (bradycardia).
- Shortness of breath, cough, interstitial lung disease (a group of disorders that cause progressive scarring of lung tissue).
- Chest pain, symptoms of weakness, flu-like illness.
- Abnormal liver function (causing yellowing of the skin and whites of the eyes), discomfort in the abdomen.
- Kidney impairment, including kidney failure (producing less urine than is normal for you).
- Sepsis (often called blood poisoning, a severe infection with whole body inflammatory response which can lead to death).

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

Tell your doctor as soon as possible if you notice any of the following:
Side effects occurring less frequently:

- Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold).
- Urinary tract infections.
- Deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia).
- High potassium levels in the blood, low blood sugar levels (in diabetic patients).
- Abdominal pain, diarrhoea, vomiting (being sick), dry mouth, upset stomach, passing gas, change in sense of taste, indigestion.
- Increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the

blood, decreased haemoglobin.
- Muscle pain (myalgia) or cramps, joint pain (arthralgia), back pain, pain in extremity, tendon pain (symptoms like inflammation of the tendons).
- Weakness, lack of energy.
- Sudden drop in heart rate and blood pressure, causing fainting, paleness and a rapid heartbeat.
- Dizziness when standing up (orthostatic hypotension), feeling of spinning (vertigo), low blood pressure.
- Feeling anxious, feeling sad (depression), difficulty falling asleep.
- Sleepiness, feeling drowsy.
- Increased sweating, redness of skin, medicinal rash, eczema (a skin disorder), itching, hives (urticaria).
- Impaired vision.

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 **"6.04 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 ADCO TELMISARTAN.

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

5. How to store ADCO TELMISARTAN

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- 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 ADCO TELMISARTAN contains

The active substance is telmisartan.

ADCO TELMISARTAN 20: Each tablet contains 20 mg telmisartan.

ADCO TELMISARTAN 40: Each tablet contains 40 mg telmisartan.

ADCO TELMISARTAN 80: Each tablet contains 80 mg telmisartan.

The other ingredients are sodium hydroxide, povidone (K 25), meglumine, mannitol (E 421), magnesium stearate and crospovidone.

What ADCO TELMISARTAN looks like and contents of the pack

Tablets.

ADCO TELMISARTAN 20: White, round, bevelled tablets with “LC” embossed on one side, 7 mm in diameter.

ADCO TELMISARTAN 40: White oblong tablets with “LC” embossed on one side, approximately 12,0 x 5,9 mm in size.

ADCO TELMISARTAN 80: White oblong tablets with “LC” embossed on one side, approximately 16,0 x 8,0 mm in size.

ADCO TELMISARTAN tablets are packaged in silver aluminium/aluminium blister packs.

Blister packs of 14, 28, 30, 56, 84, 90, or 98 tablets are available.

Not all pack sizes may be marketed.

The blister strips are packed in a cardboard outer carton.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

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