PATIENT INFORMATION LEAFLET

TESDYN RANGE

SCHEDULING STATUS

S3

TESDYN 40/5 mg tablets

TESDYN 40/10 mg tablets

TESDYN 80/5 mg tablets

TESDYN 80/10 mg tablets

Telmisartan and Amlodipine (as Amlodipine Besylate)

TESDYN 40/5 mg contains sugar alcohol – mannitol 169,94 mg/tablet.

TESDYN 40/10 mg contains sugar alcohol – mannitol 169,94 mg/tablet.

TESDYN 80/5 mg contains sugar alcohol – mannitol 339,88 mg/tablet.

TESDYN 80/5 mg contains sugar alcohol – mannitol 339,88 mg/tablet.

Read all of this leaflet carefully before you start taking TESDYN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TESDYN 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 TESDYN is and what it is used for
2. What you need to know before you take TESDYN
3. How to take TESDYN
4. Possible side effects
5. How to store TESDYN
6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET

TESDYN RANGE

1. What TESDYN is and what it is used for

TESDYN tablets contain two active substances called telmisartan and amlodipine. Both of these substances help to control your high blood pressure:

- Telmisartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is a substance produced in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.
- 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. This means that both of these active substances work together to help stop your blood vessels tightening.

As a result, the blood vessels relax and blood pressure is lowered.

TESDYN is used for high blood pressure in adult patients:

- whose blood pressure is not controlled enough with amlodipine alone.
- who already take and are controlled on telmisartan and amlodipine as separate tablets at the same dose.

2. What you need to know before you take TESDYN

Do not take TESDYN:

- if you are hypersensitive (allergic) to telmisartan, amlodipine, dihydropyridine derivatives (one type of calcium channel blocker), or to any of the ingredients of TESDYN (see Section 6)
- if you have developed swelling and giant wheals on your skin when having previously taken medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs)
- if you or anyone else in your family have been diagnosed with idiopathic angioedema - a disorder characterized by recurrent episodes of severe swelling under the skin

- if you have an enlarged heart muscle (hypertrophic obstructive cardiomyopathy (HOCM))
- if you have severe kidney disease
- if you have a disease which narrows your kidney arteries (bilateral renal artery stenosis)
- if you have only one kidney or you suffer from or a narrowing or blockage of the arteries that supply blood to your kidney (renal artery stenosis)
- if you have a disease which narrows heart's arteries (aortic stenosis)
- if you are taking other medicines, which increase the potassium levels in your blood (e.g. certain types of diuretics/water tablets, such as spironolactone, triamterene, amiloride and potassium supplements). These medicines are usually used to treat high blood pressure or swelling
- if you have porphyria, a rare disease of a deficiency of certain enzymes. The disease can be recognised by nerve pain and skin problems
- if you are on lithium therapy (a medicine used to treat some types of depression)
- if you are pregnant or breastfeeding your baby
- If you are treated with a blood pressure lowering medicine containing aliskiren
- if you have severe liver problems or biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder)
- if you suffer from cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you are treated with fluoroquinolone antibiotic such as ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin and norfloxacin.

Warnings and precautions

Take special care with TESDYN:

- if you fall pregnant while taking TESDYN, therapy should be stopped immediately and switched to a different class of high blood pressure medicine

- if you are taking medicines which contain aliskiren. You should not take these medicines with TESDYN (see Do not take TESDYN)
- if you suffer from liver problems
- if you have been told that you have a narrowing of your kidney arteries and/or only have one kidney and the arteries are narrow
- if you have kidney problems and if you had a kidney transplant
- if you are on a low-salt diet, have lost a lot of fluids recently (due to excessive sweating, hot weather, exercising, diarrhoea, vomiting or dialysis) or are taking high doses of water tablets as you may experience dehydration or a serious drop in blood pressure (hypotension) with symptoms including feeling dizzy when standing up
- if you have had heart failure, have experienced a heart attack, or have kidney problems, follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function
- if you have low blood pressure (acute), high levels of urea in your blood (as determined by blood tests), less urination than normal and kidney failure
- if you suffer from kidney problems and are taking a fluoroquinolone antibiotic, your doctor will need to assess your condition before starting and during treatment with TESDYN
- if you are already taking a fluoroquinolone antibiotic together with TESDYN you should contact your doctor to re-evaluate your treatment
- if you have been told that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- if your doctor has told you that you have a narrowing of the valves in your heart (called aortic or mitral stenosis) or that the thickness of your heart muscle is abnormally increased (called obstructive hypertrophic cardiomyopathy)
- if you have high potassium levels in your blood or use salt substitutes that contain potassium
- if you have diabetes.

Your doctor may check your kidney function, blood pressure, and the amounts of electrolytes (e.g. potassium) in your blood at regular intervals during treatment.

Other medicines and TESDYN

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Please tell your healthcare provide if you take:

- Aliskiren and similar medicines as unwanted side effects such as low blood pressure, increased potassium levels in the blood and kidney problems including kidney failure may increase
- Fluoroquinolone antibiotics as taking these with TESDYN may cause kidney problems
- Other medicines to treat high blood pressure, including water tablets, or medicines with blood pressure lowering potential like baclofen (used to treat muscle spasms caused by certain conditions like spinal cord injury) and amifostine (medicine used in cancer treatment)
- Antidepressants, barbiturates (medicine use to treat sleeplessness and seizures), narcotics (used to treat severe pain) or alcohol as the effects of TESDYN may increase and result in low blood pressure when standing up (may cause temporary dizziness)
- Corticosteroids (used to treat inflammation), as the effect of TESDYN may be lowered
- Potassium-sparing medicines (water tablets), potassium supplements, or salt substitutes containing potassium as the way these medicines work may be affected by TESDYN and can increase potassium levels in the blood.
- Lithium (a mood stabiliser) and other anti-depressants as the levels of these may be increased by TESDYN and result in toxicity
- Certain types of painkillers called Non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors) to treat pain and arthritis (such

as ibuprofen, indomethacin or aspirin), as these may reduce the blood pressure lowering effect of TESDYN and may affect the kidney function or worsen an existing kidney problem

- Digoxin (used to treat heart conditions) as the effect of digoxin may increase
- Diltiazem (used to prevent chest pain and lower high blood pressure) as this may increase the effect of TESDYN if you are elderly
- Medicines to treat fungal infections (such as ketoconazole, itraconazole) or an HIV medicine ritonavir, may increase the effects of the active ingredient amlodipine contained in TESDYN and you dose may need to be adjusted
- Anti-convulsant medicines (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone), rifampicin (antibiotic used to treat tuberculosis (TB)), or St John's Wort (an herbal medicine), as you doctor will need to monitor your blood pressure and dose of TESDYN
- Simvastatin (a medicine used to control high cholesterol levels) as the effect may be increased when taking TESDYN at the same time. Your dose of simvastatin may need to be adjusted
- Ciclosporin or tacrolimus (medicine used to suppress your immune system) as the effect of TESDYN may be increased.

TESDYN with food and drink

TESDYN can be taken with or without food. Grapefruit and grapefruit juice should not be consumed as the effects of TESDYN may be enhanced. Do not drink alcohol with TESDYN as the effect of lowering your blood pressure when getting up from a laying or sitting position (you may feel faint or dizzy), may worsen.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using TESDYN.

Women of childbearing age should ensure effective contraception.

TESDYN should not be taken while you are pregnant as it may be hazardous to the developing baby (see Do not take TESDYN).

If you plan to get pregnant, consult your doctor to change you on to an alternative high blood pressure medicine, which is safe for use in pregnancy.

Do not breastfeed your baby when using TESDYN. Amlodipine (as contained in TESDYN) has been shown to pass into breast milk in small amounts.

Driving and using machines:

TESDYN has a moderate influence on your ability to drive or operate machinery. Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive or operate machinery.

It is not always possible to predict to what extent TESDYN may interfere with your daily activities. You should ensure that they do not engage in the above activities until they are aware of the measure to which TESDYN affects them.

3. How to take TESDYN

Do not share medicines prescribed for you with any other person. Always use TESDYN exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one tablet daily, with or without food.

If your liver is not working properly, the usual dose should not exceed TESDYN 40/5 mg or TESDYN 40/10 mg once daily.

Children:

TESDYN is not recommended for use in patients aged below 18 years.

Your doctor will tell you how long your treatment with TESDYN will last. Do not stop treatment early because your high blood pressure may return.

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

If you take more TESDYN 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.

Symptoms of overdose may include:

- low blood pressure and rapid heartbeat, slow heartbeat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

If you forget to take TESDYN:

If you forget to take TESDYN, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TESDYN

It is important that you take TESDYN every day until your doctor tells you otherwise.

4. Possible side effects

TESDYN can have side effects.

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

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

- swelling of the 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 TESDYN. 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 which may occur when taking either TESDYN or telmisartan or amlodipine alone:

- changes in the way your heart beats, for example, if you notice it is beating slower/faster than normal, or irregular and rapid causing poor blood flow
- heart attack (symptoms include tightness or pain in the chest, neck back or arms, fatigue, abnormal heartbeat
- Toxic epidermal necrolysis (TEN) (a life-threatening skin disorder with symptoms such as a painful red area that spreads quickly, skin peeling without blisters, raw areas of skin) or

Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)

- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite, jaundice (yellow discolouration of the skin and eyes))
- sepsis (a life-threatening complication of an infection)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness
- cough
- general swelling (e.g. swelling of the arms, hands, legs, ankles or feet)

Less frequent side effects:

- cystitis (inflammation of the bladder)
- depression, anxiety and sleeplessness
- sleepiness, migraine, headache, tingling or numbness of the hands or feet (pins and needles sensation), weakness, numbness, pain, distortion of taste, tremor
- spinning sensation, loss of balance (vertigo)
- low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing
- dry cough, shortness of breath due to lung disease
- stomach pain, diarrhoea, nausea, vomiting, indigestion, dry mouth, gum enlargement
- skin conditions ranging from a rash, eczema, hives, itchy skin
- back pain, muscle spasm, muscle pain, joint, arm or leg pain
- unusual waking up during the night to urinate

- inability to get or maintain an erection (erectile dysfunction)
- lack of energy or strength, fatigue, general feeling of discomfort, swelling (oedema), chest pain
- increased levels of liver enzymes, increased levels of uric acid in the blood
- urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- deficiency in red blood cells (anaemia), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia)
- high blood potassium levels, low blood sugar (in diabetic patients)
- disturbances in vision
- shortness of breath (dyspnoea)
- flatulence, stomach discomfort
- abnormal liver function, liver problems
- increased sweating, hives (urticaria), rash
- tendon pain
- kidney problems
- flu-like illness
- increased levels of creatinine in the blood, decreased haemoglobin (a blood protein), increased levels of creatine phosphokinase in the blood.

Frequency unknown:

- low number of white cells in the blood (leukopenia)
- excess sugar in blood
- mood changes, confusion
- abnormal muscle movements
- ringing in the ears

- inflammation of the blood vessels
- sneezing/running nose
- change of bowel habit, inflamed pancreas, abdominal bloating (gastritis)
- yellowing of the eyes and skin, increased liver enzymes
- hair loss, unusual bruising and bleeding (red blood cell damage), skin discolouration, rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), peeling of the skin (exfoliative dermatitis), sensitivity to sunlight
- ankle swelling
- difficulty passing urine, frequent, abnormal urination during the day
- enlarging of male breasts
- pain, weight increased, weight decreased

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 or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TESDYN. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store TESDYN

Store all medicines out of reach of children.

Store at or below 30°C.

Protect from moisture and light.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TESDYN contains

TESDYN 40/5 mg: Each tablet contains 40 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

TESDYN 40/10 mg: Each tablet contains 40 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

TESDYN 80/5 mg: Each tablet contains 80 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

TESDYN 80/10 mg: Each tablet contains 80 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

The other ingredients are:

Corn starch, crospovidone, FD & C Blue/Brilliant Blue, iron oxide black, magnesium stearate, mannitol, meglumine (for pH-adjustment), microcrystalline cellulose, povidone, sodium hydroxide (for pH-adjustment), sodium stearyl fumarate.

What TESDYN looks like and contents of the pack

TESDYN 40/5 mg: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with ‘L389’.

TESDYN 40/10 mg: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with ‘L390’.

TESDYN 80/5 mg: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with ‘L391’.

TESDYN 80/10 mg: Oval shaped biconvex, Bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with ‘L388’.

TESDYN is packed into blister packs of 30 tablets as aluminium foil (child resistant) and cold form blister foil or aluminium foil and cold form blister foil.

Holder of Certificate of Registration

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