PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM

TREMISTAN PLUS 40/12,5 (film-coated tablets)
TREMISTAN PLUS 80/12,5 (film-coated tablets)
TREMISTAN PLUS 80/25 (film-coated tablets)

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TREMISTAN 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.

1. WHAT TREMISTAN PLUS CONTAINS

Active ingredient:

Tremistan Plus 40/12,5: Each film-coated tablet contains 40 mg telmisartan and 12,5 mg hydrochlorothiazide.
Tremistan Plus 80/12,5: Each film-coated tablet contains 80 mg telmisartan and 12,5 mg hydrochlorothiazide.
Tremistan Plus 80/25: Each film-coated tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

Inactive ingredients:

Each Tremistan Plus 40/12,5 film-coated tablet contains citric acid monohydrate, ferric oxide (yellow 10) E172, ferric oxide (red 30) E172, lactose anhydrous, ludipress (lactose based excipient)*, macrogol poly (vinyl alcohol) grafted copolymer, magnesium stearate, meglumine, povidone K25 and sodium hydroxide.

Each Tremistan Plus 80/12,5 film-coated tablet contains citric acid monohydrate, lactose anhydrous, ludipress (lactose based excipient)*, macrogol poly (vinyl alcohol) grafted copolymer, magnesium stearate, meglumine, povidone K25 and sodium hydroxide

Each Tremistan Plus 80/25 film-coated tablet contains citric acid monohydrate, ferric oxide (yellow 10) E172, lactose anhydrous, ludipress (lactose based excipient)*, macrogol poly (vinyl alcohol) grafted copolymer, magnesium stearate, meglumine, povidone K25 and sodium hydroxide.

* Ludipress consists of 93 % lactose monohydrate, 3,5 % povidone K30 and 3,5 % crospovidone type A.

Each Tremistan Plus 40/12,5 film-coated tablet contains sugar (lactose 155,24 mg).
Each Tremistan Plus 80/12,5 film-coated tablet contains sugar (lactose 310,48 mg).
Each Tremistan Plus 80/25 film-coated tablet contains sugar (lactose 310,48 mg).

2. WHAT TREMISTAN PLUS IS USED FOR

TREMISTAN PLUS is a combination of two active ingredients, telmisartan and hydrochlorothiazide in one tablet. It belongs to a group of medicines known as anti-hypertensive medicines.

Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause urine output to increase leading to a lowering of blood pressure.

TREMISTAN PLUS 40 /12,5, 80 /12,5 and 80/25 is used to treat high blood pressure (hypertension).

3. BEFORE YOU TAKE TREMISTAN PLUS

Do not take TREMISTAN PLUS:

- If you are allergic (hypersensitive) to telmisartan, hydrochlorothiazide or any of the ingredients of TREMISTAN PLUS (see “WHAT TREMISTAN PLUS CONTAINS”).
- If you are allergic (hypersensitive) to a group of medicines called sulphonamides.
- If you ever developed angioedema, which is swelling of the face, lips, mouth, tongue, throat, limbs or any other part of your body, and giant wheals on your skin when previously taking medicines called angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- If you ever developed angioedema for any other reason (see the point above for a description of angioedema).
- If you have hypertrophic obstructive cardiomyopathy, which is a disease in which a portion of the myocardium (heart muscle) is enlarged without any obvious cause, creating impairment of the heart.
- If you have any kidney disorders.
- If you have any narrowing of the arteries that carry blood to your kidneys (renal artery stenosis).
- If you have aortic stenosis, which is narrowing of the aortic valve in the heart. This leads to restricted blood flow through the valve and causes the heart then to squeeze (contract) harder to pump blood into the aorta.
- If you are being treated with potassium sparing diuretics (medication used to lower your blood pressure), such as spironolactone, triamterene and amiloride.
- If you are taking any potassium supplements, salt substitutes containing potassium or medicine that increases potassium levels in your blood e.g. heparin.
- If you have a condition called porphyria, which is a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin. Porphyrins are excreted in the urine, which becomes dark; other symptoms include mental disturbances and extreme sensitivity of the skin to light.

- If you are receiving lithium therapy, used to treat bipolar disorders. Simultaneous administration with TREMISTAN PLUS may lead to toxic blood concentrations of lithium.
- If you are pregnant or breastfeeding.
- If you are using medicines called aliskiren, used to treat primary essential hypertension.
- If you are using a group of medicine called ACE inhibitors or angiotensin II receptor blockers (ARB's) used to treat primary essential hypertension if you have diabetes mellitus and have kidney problems.
- Obstruction of the bile ducts (bile helps rid the liver of waste products).
- If you have any liver disorders.
- If you have abnormal low levels of potassium in your blood (which includes the following symptoms: abnormal heart rhythms (especially in people with heart disease), constipation, unusual weakness or tiredness, muscle weakness or spasms).
- If you have abnormal low levels of sodium in your blood (characterised by nausea, vomiting, headache, confusion, lethargy, fatigue, appetite loss, restlessness, irritability, muscle weakness, muscle spasms, muscle cramps or seizures).
- If you have higher than normal levels of calcium in your blood (which includes symptoms of constipation, weakness, tiredness, pain in your bones, kidney stones, nausea, vomiting and increased urination).
- If you have high levels of uric acid in your blood. Symptoms includes pain, inflammation, swelling, redness, and tenderness when touched. Many people also say that the joint feels "hot". One of the most common areas affected by gout is your big toe.

Take special care when taking TREMISTAN PLUS if:

- If you are pregnant or planning to become pregnant. Contact your doctor as soon as possible (see "Do not take TREMISTAN PLUS").
- If you are using a group of medicine called ACE inhibitors or angiotensin II receptor blockers (ARB's) used to treat primary essential hypertension together, this should only be under supervision of your doctor.
- If you have heart failure (see "Do not take TREMISTAN PLUS").
- If you had a kidney transplant.
- If your body has lost fluids and electrolytes, for example, if you are taking diuretics ("water tablets"), taking little salt in your diet or had diarrhoea and vomiting. Warning signs or symptoms of fluid and electrolyte loss are dryness of the mouth, thirst, weakness, slowness, drowsiness, restlessness, confusion, seizures (fits), muscle pains or cramps, muscular fatigue, low blood pressure, urinating less than normal and a fast heartbeat.
- If you have a condition called primary aldosteronism (an overproduction of the hormone aldosterone, leading to high blood pressure).
- If you suffer from mitral valve stenosis which is a narrowing of the heart's mitral valve. This abnormal valve doesn't open properly, blocking blood flow into the main pumping chamber of your heart (left ventricle). Mitral valve stenosis can make you tired and short of breath.
- If you have hyperkalaemia (abnormal high levels of potassium in your blood).
- If you have abnormal low levels of chloride in your blood.

- If you have hypomagnesaemia (abnormal low level of magnesium in your blood).
- If you are a black person, as it may be less effective in lowering your blood pressure.
- If you have diabetes mellitus (high blood sugar) as dosage adjustments of your diabetic medicine may be needed.
- If you have high cholesterol or triglyceride (a type of fat) levels in your blood.
- If you have systemic lupus erythematosus (an autoimmune disorder), use TREMISTAN PLUS with caution as TREMISTAN PLUS may worsen your condition.
- If you are taking TREMISTAN PLUS, you may have a higher risk of developing non-melanoma skin cancer (a type of skin cancer). Signs may include sores that do not heal, spread of pigment from the border of a spot into surrounding skin, redness or a new swelling beyond the border of the mole, change in sensation, such as itchiness, tenderness, or pain.
- If you suffer from allergy or asthma as hydrochlorothiazide may cause allergic reactions in some patients.
- If you experience a sensitivity reaction to light, it is recommended to protect exposed areas to the sun.
- If you feel pain in your eyes, have vision problems or have a history of sulphonamide or penicillin allergy.

Taking TREMISTAN PLUS with food or drink:
TREMISTAN PLUS can be taken with or without food.

Pregnancy and Breastfeeding:
Do not take TREMISTAN PLUS if you are pregnant, are considering becoming pregnant or are breastfeeding.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking TREMISTAN PLUS.
A switch to a sustainable alternative treatment should be carried out in advance of planned pregnancy.

Driving and using machinery:
- TREMISTAN PLUS may make you feel drowsy/sleepy.
- Take special care before driving or operating machinery until you know how TREMISTAN PLUS will affect you.

Important information about some of the ingredients of TREMISTAN PLUS:
TREMISTAN PLUS contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take TREMISTAN PLUS.

TREMISTAN PLUS contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with TREMISTAN PLUS:

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

Tell your doctor if you are taking any of the following medicines:

- Lithium (used to treat mood disorders) (see “Do not take TREMISTAN PLUS”).
- Renin inhibitors such as aliskiren, (for treatment of high blood pressure) (see “Do not take TREMISTAN PLUS) if you have diabetes mellitus and you have kidney problems.
- ACE-inhibitors, ARBs and other antihypertensive medicines (used in the treatment of high blood pressure) can cause excessive low blood pressure when used concomitantly (see “Do not take TREMISTAN PLUS”).
- Diuretics (water pills used to treat high blood pressure).
- Potassium sparing diuretics such as spironolactone, triamterene and amiloride, potassium supplements, salts containing potassium or other medicine that may increase the potassium levels e.g. heparin, an anticoagulant (blood thinner) used to treat blood clots. (see “Do not take TREMISTAN PLUS).
- Non-steroidal anti-inflammatory drugs (used to treat pain and inflammation).
- Aspirin (used in the treatment of pain, fever and inflammation).
- Digoxin (used to treat heart failure).
- Cyclophosphamide (used to treat various types of cancer).
- Methotrexate (used to treat rheumatoid arthritis or psoriasis).
- Baclofen used to treat muscle spasms caused by certain conditions (such as multiple sclerosis).
- If you take amifostine, used to treat cancer.
- Methyldopa (used to treat high blood pressure).
- Amantadine (used in the treatment and prevention of flu or for the treatment of Parkinsonism).
- Alcohol.
- Barbiturates (used in the treatment of epilepsy/fits) or narcotics such as morphine or codeine (used to treat pain.)
- Antidepressants.
- Metformin (insulin or other antidiabetic medicines) (used in the treatment of diabetes).
- Cholestyramine or cholestipol (used to lower high cholesterol levels in the blood).
- Pressor amines (medicines to raise blood pressure, e.g. noradrenaline).
- Muscle relaxants such as tubocurarine or baclofen.
- Probenecid, sulfinpyrazone or allopurinol (used in the treatment of gout).
- Calcium salts (used as calcium supplement).
- Vitamin D containing products such as salmon, tuna, eggs or milk.
- Beta-blockers (used to treat heart conditions, such as high blood pressure, abnormal heart rhythms, chest pain or glaucoma).

- Diazoxide (used to treat low blood sugar [hypoglycaemia]).
- Atropine (used to dilate the pupils in eye examinations).
- Biperidine (used in the treatment of Parkinsonism).
- Antidysrhythmic medicines (used in the treatment of abnormal rhythms of the heart) such as quinidine and disopyramide.
- Penicillin, erythromycin, clarithromycin, moxifloxacin (antibiotics used in the treatment of bacterial infection).
- Halofantrin (used in the treatment of malaria).
- Dolasetron (used to treat nausea and vomiting following chemotherapy).
- Chlorpromazine, pimozide and droperidol (used in the management of psychosis which include delusions, hallucinations and disordered thoughts).
- Mizolastin (used in the treatment of hives).
- Laxatives (used to treat constipation).
- Corticosteroids (used in the treatment of inflammation).
- Adrenocorticotropic hormone (ACTH) receptor agonists such as corticotropin which causes your body to produce a substance called cortisol, which affects your immune system and helps to decrease inflammation.
- Amphotericin B (used in the treatment of systemic fungal infections).
- Carbenoxolone (used in the treatment of inflammation and ulcers in the oesophagus).
- Salicylic acids containing products (used to treat warts, psoriasis, dandruff, acne, ringworm and ichthyosis).

4. HOW TO TAKE TREMISTAN PLUS

Do not share medicines prescribed for you with any other person.
Always take TREMISTAN PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Your doctor will determine the correct dose for your condition.
TREMISTAN PLUS tablets can be taken once daily.
TREMISTAN PLUS should be swallowed whole with a glass of water, can be taken with or without food.
Your doctor may prescribe TREMISTAN PLUS in combination with other blood pressure lowering medicines.

The best blood pressure lowering result is achieved at least four weeks after the start of treatment with TREMISTAN PLUS.

Your doctor will tell you how long your treatment with TREMISTAN PLUS will last. Do not stop treatment early because it could worsen your condition.
If you have the impression that the effect of TREMISTAN PLUS is too strong or too weak, tell your doctor or pharmacist.

In children and adolescents up to the age of 18 years:
Safety and efficacy has not been established in children and adolescents, and it is therefore not recommended that anyone younger than 18 years of age should take TREMISTAN PLUS.

If you take more TREMISTAN 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. Symptoms of a possible overdose may include:

- Low blood pressure.
- Fast heartbeat.
- Sometimes a slower heartbeat.
- Dizziness.
- Chest pain, trouble breathing.
- Dehydration, diarrhoea.
- Nausea, vomiting.
- Excessive drowsiness.
- Muscle spasms.
- Irregular heartbeat.

If you forget to take a dose of TREMISTAN PLUS:
Take TREMISTAN PLUS as soon as you remember. If it is almost time for your next usual dose, skip the missed dose and continue taking TREMISTAN PLUS at your regular time. Do not take a double dose of TREMISTAN PLUS to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

TREMISTAN PLUS can have side effects.
Not all side effects reported for TREMISTAN PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TREMISTAN PLUS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking TREMISTAN PLUS 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.
- Skin rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TREMISTAN 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:

- Chest pain.
- Fainting.

- Yellowing of the skin and eyes, also called jaundice, including nausea, vomiting, stomach pain and discomfort, loss of appetite, generally feeling unwell, fever, itching, light coloured stools and dark coloured urine. These symptoms might be an indication of a liver disease.
- Changes in the way your heart beats, for example, you notice it beating faster or very slow.
- Producing less urine than is normal for you.
- Fever, abdominal pain, tenderness when touching the abdomen.
- Decreased urine, patches of discoloured skin, trouble breathing, unconsciousness.

These are all serious side effects. You may need urgent medical attention. The frequency of these serious side effects is not known.

Tell your doctor as soon as possible if you notice any of the following:

***Side effects occurring frequently*:**

- Dizziness

***Side effects occurring less frequently*:**

- Low blood pressure or dizziness on standing up, especially when getting up from a sitting or lying position.
- Light-headedness/spinning sensation.
- Changes in the number of different cells in your blood, which may present as tiredness, new infections, fever and easy bruising or bleeding that can sometimes look like a rash of purple spots under the skin.
- Muscle cramps, cramps in the legs, leg pain, back pain, weakness, which may be signs of hypokalaemia (abnormal low level of potassium in your blood).
- Excessive drowsiness or weakness.
- Diarrhoea, dry mouth, flatulence or wind, abdominal pain, constipation, stomach discomfort. These may be signs of a gastrointestinal disorder.
- Nausea and vomiting, headache, confusion, loss of energy and fatigue. Restlessness and irritability. Muscle weakness, spasms or cramps. Seizures or coma. These might be signs of hyponatraemia, where there is an abnormal low level of sodium in your blood.
- Fever, blood in the urine, exhaustion, confusion, fatigue, nausea, vomiting which may be signs of bladder infection.
- Increased sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat, which may be symptoms of hypoglycaemia (low sugar/glucose) levels in the blood.
- Fatigue, breathing problems, numbness, chest pain, palpitations or skipped heartbeats, which may be symptoms of hyperkalaemia (abnormal high levels of potassium in the blood)
- Anxiety or depression
- Abnormal or blurred vision, severe eye pain seeing rainbow-colored circles around bright lights, vision deficiency in which there is a predominance of yellow in vision, a condition called xanthopsia.
- Impotence, the inability to maintain an erection.
- Trouble sleeping, sleep disturbances,

- Infections of your upper airways, including infections of your lungs, throat and sinuses.
- Flu-like symptoms.

***Side effects frequency unknown*:**

- Fever, headaches, weight loss, general aches, night sweats and rash may be symptoms of vasculitis (inflammation of blood vessel/vessels).
- Blood poisoning (including fatal outcome).
- Worsening or activation of systemic lupus erythematosus, a disease where the body's tissues are attacked by its own immune system. Some of the symptoms include: butterfly rash on the face, sensitivity of the skin to sunlight, tender swollen joints, ulcers in the mouth, nose and throat.
- Redness and inflammation of the skin.
- Pharyngitis, sinusitis.
- Anorexia, loss of appetite.
- Abnormal or foul taste in your mouth.
- Increased thirst, headaches, trouble concentrating, blurred vision, fatigue, urinating more than usual, weight loss, which may be signs of hyperglycaemia (abnormal high level of glucose in your blood).
- Restlessness.

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

6. STORING AND DISPOSING OF TREMISTAN PLUS

Store at or below 25 °C.
Keep blisters in the outer carton until required for use.
TREMISTAN PLUS tablets should not be removed from the blister strips until required for use in order to protect from moisture.
Do not use after the expiry date stated on the label.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF TREMISTAN PLUS

Tremistan Plus 40/12,5: Silver aluminium/aluminium blister strips containing 7 tablets each or silver aluminium/aluminium blister strips containing 14 tablets each.
Pack size 28’s.
Tremistan Plus 80/12,5: Silver aluminium/aluminium blister strips containing 7 tablets each or silver aluminium/aluminium blister strips containing 14 tablets each.
Pack size 28’s.
Tremistan Plus 80/25: Silver aluminium/aluminium blister strips containing 7 tablets each or silver aluminium/aluminium blister strips containing 14 tablets each.
Pack size 28’s.

8. IDENTIFICATION OF TREMISTAN PLUS

Tremistan Plus 40/12,5: red, oval, biconvex film-coated tablet debossed with 40 on one side and with 12,5 on the other side.
Tremistan Plus 80/12,5: white to off-white, oval, biconvex film-coated tablet debossed with 80 on one side and with 12,5 on the other side.
Tremistan Plus 80/25: yellow, oval, biconvex film-coated tablet debossed with 80 on one side and with 25 on the other side.

9. REGISTRATION NUMBERS

Tremistan Plus 40/12,5: 46/7.1.3/0927
Tremistan Plus 80/12,5: 46/7.1.3/0928
Tremistan Plus 80/25: 46/7.1.3/0929

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION:

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