PATIENT INFORMATION LEAFLET FOR TELZA

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TELZA 20, TELZA 40 and TELZA 80 mg Film coated tablets

Telmisartan

TELZA 20 contains sugar (lactose monohydrate, 108,68 mg)

TELZA 40 contains sugar (lactose monohydrate, 217,35 mg)

TELZA 80 contains sugar (lactose monohydrate, 434,70 mg)

TELZA 20 contains salt (sodium, 0,96 mg)

TELZA 40 contains salt (sodium, 1,93 mg)

TELZA 80 contains salt (sodium, 3,85 mg)

Read this entire leaflet carefully before you start taking TELZA.

- 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.
- TELZA 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 TELZA is and what it is used for
2. What you need to know before you take TELZA
3. How to take TELZA
4. Possible side effects
5. How to store TELZA

6. Contents of the pack and other information

1. What TELZA is and what it is used for

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

TELZA tablets are used for the treatment of high blood pressure in adults.

TELZA tablets can also be used to reduce cardiovascular events (i.e. heart attack or stroke) and death in patients 55 years or older who are at high risk of cardiovascular disease.

2. What you need to know before you take TELZA

Do not take TELZA:

- If you are allergic to telmisartan or any of the other ingredients of TELZA (see section 6)
- If you have developed swelling of the face, lips, mouth, tongue or throat 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 your doctor has told you that the thickness of your heart muscle is abnormally increased (hypertrophic obstructive cardiomyopathy (HOCM))
- If you suffer from obstruction of blood vessels to your heart or kidneys
- If you have severe kidney function problems
- If you are currently taking potassium sparing diuretics (‘water tablets’) containing spironolactone, triamterene or amiloride

- If you have porphyria (a rare hereditary disease)
- If you are currently taking lithium (used to treat some types of depression)
- Do not take TELZA if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.
- If you suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- If you are currently taking aliskiren-containing products
- If you are taking a fluoroquinolone antibiotic (used to treat a variety of illnesses such as respiratory and urinary tract infections) if you have kidney problems or are elderly.

Warnings and precautions

Take special care with TELZA and tell your doctor:

- If you become pregnant while taking TELZA. You should stop treatment immediately and contact your doctor to change your medicine.
- If you suffer from kidney disease or have had a kidney transplant
- If your body could be lacking in salt due to a low salt diet, or if you have recently lost a lot of body fluids due to taking diuretic medicines (water tablets), vomiting or diarrhoea
- If you are already taking a medicine called an angiotensin-converting enzyme (ACE) inhibitor
- Contact your doctor to re-evaluate your treatment if you are treated with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.
- If you have been told previously that you have raised aldosterone levels
- If you have heart problems
- If you have diabetes
- If you have high potassium levels in your blood or use salt substitutes containing

potassium

- If you have liver problems.

Children and adolescents

The safety and efficacy of TELZA for use in children below 18 years have not been established.

Other medicines and TELZA

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

Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with TELZA:

- Digoxin (used to treat various heart conditions)
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. ciclosporin or tacrolimus), and the antibiotic trimethoprim.
- Lithium containing medicines (used to treat some types of depression).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “**Do not take TELZA**” and “**Warnings and precautions**”
- Diuretics ('water tablets'), especially if taken in high doses together with TELZA, may lead to excessive loss of body water and low blood pressure (hypotension).

The effect of TELZA may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

TELZA may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine).

Concomitant use of fluoroquinolones and TELZA may precipitate acute kidney injury.

Furthermore, alcohol, barbiturates, narcotics or antidepressants may aggravate low blood pressure. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking TELZA.

TELZA with food, drink and alcohol

TELZA can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant, 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 TELZA.

Do not take TELZA if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines

When driving vehicles or operating machinery, it should be taken into account that dizziness or drowsiness may occur when taking blood pressure lowering medication including TELZA. You should not engage in the above activities until you are aware of the extent to which TELZA affects you.

TELZA contains sugar (lactose monohydrate) and salt (sodium)

TELZA contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TELZA.

This medicine contains less than 23 mg per tablet, that is to say essentially 'sodium-free'.

3. How to take TELZA

Do not share medicines prescribed for you with any other person. Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is 40 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water. The dose may be increased to 80 mg in cases where the target blood pressure is not achieved.

Your doctor may prescribe TELZA in combination with other blood pressure lowering medicines.

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

If you take more TELZA 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 forget to take TELZA

Always take TELZA as prescribed. If you have missed a dose, take it as soon as

you remember. Do not take a double dose of TELZA to make up for forgotten individual doses.

If you stop taking TELZA

Do not stop taking TELZA unless your doctor tells you to.

4. Possible side effects

TELZA can have side effects.

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

If any of the following happens, stop taking TELZA 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 reaction to TELZA. 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:

- Severe, life-threatening infection (sepsis, also known as 'blood infection') with possible fatal outcome
- Changes in the way your heart beats, for example, if you notice it is beating faster, slower or irregular.
- Yellowing of the skin and eyes, dark coloured urine, feeling tired or weak which may be

symptoms of liver problems or liver failure

- Passing less urine than is normal for you which may be a sign of serious kidney problems or kidney failure.

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:

- Coughing

Less frequent side effects:

- Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- Deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia)
- High levels of potassium in your blood
- Difficulty falling asleep, feeling sad (depression), feeling anxious
- Fainting (syncope), feeling sleepy (somnolence)
- Problems with your vision
- Feeling of spinning (vertigo)
- Low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension)
- Shortness of breath, progressive scarring of lung tissue (interstitial lung disease)
- Abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, dry mouth, upset stomach, taste disturbance (dysgeusia)
- Increased sweating, itching, drug rash, eczema (a skin disorder), redness of skin
- Back pain, muscle cramps, muscle pain (myalgia), joint pain (arthralgia), pain in extremity
- Chest pain, feeling of weakness (asthenia), flu like-illness

- Increased level of creatinine in the blood, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

Side effects with unknown frequency:

- Increase in certain white blood cells (eosinophilia)
- Low blood sugar levels (in diabetic patients)
- Hives (urticaria)
- Tendon pain.

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. 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 TELZA.

5. How to store TELZA

Store all medicines out of reach of children.

Store at or below 30 ºC.

Store in the original packaging.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET FOR TELZA

What TELZA contains

TELZA 20: The active substance is 20 mg telmisartan.

TELZA 40: The active substance is 40 mg telmisartan.

TELZA 80: The active substance is 80 mg telmisartan.

The other ingredients are crospovidone, ferric oxide yellow, lactose monohydrate, magnesium stearate, meglumine, povidone K25, sodium hydroxide.
The tablet coating contains Opadry (02B82506 Yellow) consisting of ferric oxide yellow, hypromellose 5cp, macrogol (PEG-400), talc, titanium dioxide.

What TELZA looks like and contents of the pack

TELZA 20: Yellow coloured circular shaped film coated tablets with ‘20’ engraved on one side and ‘T’ engraved on other side.
TELZA 40: Yellow coloured capsule shaped film coated tablets with ‘40’ engraved on one side and ‘T’ engraved on other side.
TELZA 80: Yellow coloured capsule shaped film coated tablets with ‘80’engraved on one side and ‘T’ engraved on other side.

Silver aluminium/aluminium blister strips containing 10 tablets each, packed in an outer carton.
Pack size: 30 film coated tablets.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd
2 Waterford Mews
Waterford Place
Century City
7441

Cape Town

Tel.: +27 21 943 0600

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