NOVARTIS

# TAREG®

# 80, 160 mg

# Film-coated Tablets

# (Valsartan)

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**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S3**

**TAREG 80 mg, 160 mg Film-coated tablets**

**Valsartan**

**Sugar free**

**Read all of this leaflet carefully before you start taking TAREG**

- 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.
- TAREG 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 TAREG is and what it is used for

TAREG belongs to a class of medicines known as angiotensin-II receptor antagonists, which help to control high blood pressure.

TAREG is used to treat high blood pressure. If it continues for a long time, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure.

High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
TAREG is used to treat adult heart failure patients. Heart failure is associated with shortness of breath, and swelling of the feet and legs due to fluid build-up. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.
TAREG can also be used to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heart problems.

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. TAREG works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.
If you have any question about how TAREG works or why this medicine has been prescribed for you, ask your doctor.

**2. What you need to know before you take TAREG**

Follow your doctor's instructions carefully. They may differ from the general instructions contained in this leaflet.

**Do not take TAREG**

- If you have ever had an unusual or allergic reaction to valsartan or to any other ingredients of TAREG (listed in **section 6**).
- If you are pregnant or planning to become pregnant.
- If you have poor kidney function
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes mellitus while you are taking a blood pressure lowering medicine called aliskiren
- If you have a single kidney and have narrowing or constriction of the renal artery
- If you have too low level of potassium or sodium in your blood

- If you have too high level of calcium in your blood despite treatment
- If you have gout
- If you have porphyria
- If you have a heart condition where you have an abnormal narrowing of the aortic valve or the mitral valve
- If you have a heart condition called “hypertrophic obstructive cardiomyopathy” where the cardiac muscle is abnormally thickened and , during the contraction, it obstructs the blood flow in the left lower cavity of the heart
- If you have a history of angioedema
- If you use lithium (medicine used to treat psychiatric diseases)
- If you use potassium sparing diuretics (water pills) such as spironolactone, triamterene, amiloride
- If you have serious kidney impairment and are elderly, do not take TAREG with fluoroquinolones

If either of these apply to you, tell your doctor without taking TAREG.

If you think you may be allergic, ask your doctor for advice.

**Warnings and precautions**

Special care should be taken with TAREG:

- If you have a liver disease
- If you have a severe kidney disease or are undergoing dialysis
- If you are already taking a medicine called ACE-inhibitor (hypertension medicine) together with a beta blocker to treat your heart failure
- If you are vomiting or have diarrhoea or are taking high doses of a diuretic (water medicine).
- If you are suffering from heart failure or have experienced a heart attack. Follow your doctor’s instruction for the starting dose carefully. Your doctor may also check your kidney function.

- If you ever had a swelling mainly of the face and throat while taking other drugs (including an ACE-inhibitor). **If you get those symptoms, stop taking TAREG and contact your doctor immediately. You should never take TAREG again.**
- If you are treated with an ACE-inhibitor or aliskiren (hypertension medicine)
- Use of fluoroquinolones and ACE inhibitors/Renin-Angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients.

If any of these apply to you, tell your doctor before you take TAREG.

**Children and adolescents**

The safety and efficacy of TAREG have not been established in children.

**Other medicines and TAREG**

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

It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- Medicines used to lower blood pressure, especially diuretics (water pills), ACE-inhibitors or aliskiren (hypertension medicines);
- Potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other drugs that may increase potassium levels. Your doctor may check the amount of potassium in your blood periodically;
- Certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors). Your doctor may also check your kidney function;
- Lithium, a medicine used to treat some types of psychiatric illness;

- Some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or a drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of TAREG.

**TAREG with food and drink**

You can take TAREG with or without food.

**Pregnancy and breastfeeding**

Do not take TAREG if you are pregnant or planning to become pregnant. Use of similar medicines has been associated with serious harm to the unborn child.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor for advice before taking this medicine.
Your doctor will discuss with you the potential risk of taking TAREG during pregnancy.
Do not take TAREG while breast-feeding. Tell your doctor if you are breast-feeding.

**Driving and using machines**

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

**3. How to take TAREG**

Do not share medicines prescribed for you with any other person.
Always take TAREG exactly as your doctor or your pharmacist has told you. Check with your doctor or your pharmacist if you are not sure.

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor

even if you are feeling well. It is very important that you take this medicine exactly as your doctor or your pharmacist tells you in order to get the best results and reduce the risk of side effects.

TAREG is for oral use only.

**How much TAREG to take**

Your doctor and your pharmacist will tell you exactly how many tablets of TAREG to take.

- For adults with high blood pressure, the usual dosage is one 80 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 160 mg tablet) or an additional medicine (e.g. a diuretic).

**When to take TAREG**

Taking TAREG at the same time each day will help you remember when to take your medicine.

**How long to take TAREG**

Continue to take TAREG as your doctor or your pharmacist tells you.

If you have questions about how long to take TAREG, talk to your doctor or your pharmacist.

**If you take more TAREG than you should**

If you have accidentally taken too many tablets of TAREG, talk to your doctor or your pharmacist.

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

If you experience severe dizziness and/or fainting, tell your doctor as quickly as possible.

**If you forget to take TAREG**

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of TAREG, carry on with the next one at the usual time. Do not take a double dose to make up for the forgotten dose.

**If you stop taking TAREG**

Stopping your treatment with TAREG may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

**4. Possible side effects**

TAREG can have side effects.

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

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

Some side effects could be serious (frequency unknown: frequency cannot be estimated from the available data)

•You may experience symptoms of angioedema (an allergic reaction), such as

- swollen face, tongue or throat
- difficulty in swallowing
- hives and difficulties in breathing

If you get any of these, tell your doctor or your pharmacist immediately.

*Frequent side effects:*

- dizziness
- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

*Less frequent side effects:*

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema) - (see also “Some side effects could be serious” listed before)
- sudden loss of consciousness
- spinning sensation
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

*Frequency not known*

- blistering skin (sign of dermatitis bullous)
- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
- purplished-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)

- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes)
- increase of level of blood serum urea and increase level of serum creatinine (which can indicate abnormal kidney function)
- increased level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases) has been observed in children and adolescents 6 to 18 years of age.

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack. The following effects have also been observed during clinical trials with TAREG without possibility to determine if they are caused by the drug or have other causes: Back pain, change in libido, inflammation of the sinuses, insomnia, joint pain, pharyngitis, runny or stuffy nose, swollen hands, ankles or feet, upper respiratory tract infections, viral infections.

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, pharmacist or nurse. 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 TAREG.

**5. How to store TAREG**

KEEP OUT OF THE REACH OF CHILDREN

Do not store above 30 °C

Store your tablets in the original package

Protect from moisture

Do not use TAREG after the expiry date shown on the pack

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 TAREG contains**

- The active substance of TAREG is valsartan. The active substance of TAREG is available as film-coated tablets which contain 80 mg or 160 mg valsartan.
- The other ingredients are microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171) Macrogol 8000, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) (160 mg).

What TAREG looks like and contents of the pack

TAREG is supplied as film-coated tablets in two strengths.

TAREG 80 mg film-coated tablets are pale red, round film-coated with bevelled edges, scored on one side with debossing “D” on one side of the score and “V” on the side of the score, “NVR” on the reverse side of the tablet.

TAREG 160 mg film-coated tablets are grey-orange, ovaloid film-coated, slightly convex, scored on one side with debossing “DX” on the other side of the score, and NVR on the reverse side of the tablet.

The score line on one side of TAREG 80 mg or 160 mg FCT is only to facilitate breaking for ease of swallowing and not to divide into equal dose.

TAREG FCT is available in packs of 28 tablets in polyvinyl chloride/polyethylene/polyvinyldichloride (PVC/PE/PVDC)/ aluminium foil blisters or Polyamide/aluminium/polyvinylchloride (PA/Al/PVC)/ aluminium foil blisters.
The outer container is a printed cardboard box.

**Holder of Certificate of Registration**

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