

---

## TELEACT TABLETS

### Telmisartan 40/80 mg Tablets

---

#### What is in this leaflet

This leaflet answers some common questions about **TELEACT TABLETS**.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **TELEACT TABLETS** against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

---

#### What TELEACT TABLETS are used for

**TELEACT TABLETS** are used for the treatment of high blood pressure (also known as hypertension) in adults.

High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. This may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs, so your doctor needs to measure your blood pressure to see if it is too high.

---

#### How TELEACT TABLETS work

**TELEACT TABLETS** contain the active ingredient, telmisartan. Telmisartan belongs to a group of medicines called angiotensin-II receptor antagonist. These medicines are used to lower blood pressure. The angiotensin II antagonist (telmisartan) works by

causing blood vessels to relax, which in turn lowers blood pressure.

**Ask your doctor if you have any questions about why TELEACT TABLETS have been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

**TELEACT TABLETS** are available as 40 mg and 80 mg tablets.

**TELEACT TABLETS** are not recommended for use in children below 18 years.

---

#### Before you use TELEACT TABLETS

##### *When you must not take it*

**Do not take TELEACT TABLETS if you have an allergy to:**

- any medicine containing telmisartan
- any of the ingredients of **TELEACT TABLETS**, listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include wheezing or difficulty in breathing, shortness of breath, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

- You are more than 3 months pregnant, it could affect your unborn baby if you take it during pregnancy.
- You have severe problems with your liver (like severe hepatic impairment, biliary cirrhosis and cholestasis which manifests as yellowing of skin and whites of eyes with decreased appetite, abdominal pain, dark discolouration of urine, pale stools, fever, itchy skin).
- You have biliary obstructive disorder (problems with the drainage of the bile from the liver and gall bladder).
- You are currently breast-feeding, it is not known if

telmisartan passes into the breast milk and there is a possibility that your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

The expiry date refers to the last day of that month.

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine talk to your doctor.**

##### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- If you are pregnant.
- If you have problems with your liver.
- If you have problem with your kidneys or had kidney transplant.
- If you have renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- If you suffer from primary aldosteronism (a condition related to high production of the hormone aldosterone, which causes sodium retention and, in turn, an increase in blood pressure).
- If you have problems with your heart (significant problem with your heart valves or have a condition known as hypertrophic cardiomyopathy).
- 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.

- If you have elevated potassium levels in your blood.
- **TELEACT TABLETS** contain sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

As with all other angiotensin II receptor antagonists, **TELEACT TABLETS** may be less effective in lowering the blood pressure in black patients.

**Tell your doctor if you are pregnant or plan to become pregnant or are currently breast-feeding.**

**TELEACT TABLETS** are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

As no information is available regarding use of telmisartan during breast feeding **TELEACT TABLETS** are not recommended during breast feeding.

**If you have not told your doctor about any of the above, tell them before you start taking TELEACT TABLETS.**

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and **TELEACT TABLETS** may interfere with each other. These include:

- Lithium containing medicines to treat some types of depression.
- 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. cyclosporine or tacrolimus), and the antibiotic trimethoprim.

- Diuretics ('water tablets'), especially if taken in high doses together with **TELEACT TABLETS**, may lead to excessive loss of body water and low blood pressure (hypotension).
- Digoxin for treatment of heart failure.
- Other drugs for lowering blood pressure such as ramipril.
- Baclofen (muscle relaxant and antispastic)
- Amifostine (used to reduce the undesired side effects of certain cancer therapy)
- Alcohol, barbiturates, narcotics or drugs for the treatment of depression.
- Corticosteroids such as prednisolone (used in a wide variety of inflammatory conditions such as arthritis, colitis, asthma, bronchitis, certain skin rashes, and allergic or inflammatory conditions of the nose and eyes)

These medicines may be affected by **TELEACT TABLETS**, or may affect how well it works. Other medicines used to treat high blood pressure may have an additive effect with **TELEACT TABLETS** in lowering your blood pressure. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **TELEACT TABLETS**

### **How to take TELEACT TABLETS**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask**

**your doctor or pharmacist for help.**

### ***How much to take***

Your doctor or pharmacist will tell you how much and how often you should take **TELEACT TABLETS**.

Take the number of tablets as recommended by your doctor. The usual dose is 40 mg tablet to be taken once daily. If your blood pressure is still too high after 4-8 weeks of starting treatment, your doctor may increase your dose to 80 mg.

**TELEACT TABLETS** may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with telmisartan. For effective blood pressure lowering, your doctor may recommend 160 mg telmisartan with 12.5-25 mg hydrochlorothiazide daily.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

Your doctor may advise you to take lower dose of 20 mg a day if you are suffering from severe kidney problem or are on haemodialysis.

**TELEACT TABLET** is not recommended for use in children below 18 years.

### ***How to take it***

Swallow the tablet with a full glass of water.

You can take it with or without water.

### ***When to take it***

**Take your medicine at about the same time each day.**

Taking it at same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

Your doctor will advise you on the best time of the day to take your tablet.

### ***How long to take it***

Continue taking **TELEACT TABLETS** for as long as your doctor tells you.

**TELEACT TABLETS** helps control blood pressure; therefore **TELEACT TABLETS** must be taken every day.

### ***If you forget to take it***

**If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day.**

**Do not take a double dose to make up for forgotten individual doses.**

This may increase the chance of you getting unwanted side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TELEACT TABLETS. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much **TELEACT TABLETS**, you may feel dizzy, light-headed or faint. Your heartbeat may be faster or lower than usual. You may experience rapid, shallow breathing or cold, clammy skin. This is because your blood pressure is too low.

## **While you are taking TELEACT TABLETS**

### ***Things you must do***

Continue taking **TELEACT TABLETS** every day as directed by your doctor, even if you feel normal and do not have high blood pressure

If your condition gets worse while taking **TELEACT TABLETS**, tell your doctor immediately.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TELEACT TABLETS.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**  
You should not take this medicine while you are pregnant.

**Keep all of your doctor's appointments so that your progress can be checked.**  
Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**If you are going to have surgery, tell your doctor and anaesthetist that you are taking TELEACT TABLETS.**

**TELEACT TABLETS** may affect some medicines you receive during surgery.

### ***Things you must not do***

**TELEACT TABLETS may not be suitable for all dosages and therefore, other suitable available strengths and/or dosage forms of telmisartan should be used in such cases.**

**Do not take TELEACT TABLETS to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine because you are feeling better, unless advised by your doctor.**

### ***Things to be careful of***

**Be careful when driving or operating machinery while you are taking TELEACT TABLETS until you know how it affects you.**

Like other medicines used to treat high blood pressure, **TELEACT TABLETS** may cause sleepiness, dizziness or lightheadedness in some people.

**If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.**

## **Side Effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TELEACT TABLETS.**

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Sleeplessness
- Feelings of deep sadness and unworthiness
- Anxiety
- Spinning sensation
- Shortness of breath
- Pain in stomach
- Diarrhoea
- Vomiting
- Indigestion

- Excessive gas in stomach
- Stomach discomfort
- Dry mouth
- Muscle pain
- Back pain
- Muscle spasm
- Pain in chest
- Weakness
- Joint pain
- Pain in hands and legs
- Pain, tenderness, sometimes restricted movement (tendon pain)
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Visual disturbance
- Slow or fast heart beat
- Excessive sweating
- Redness of the skin,
- Rash,
- Itching
- Hives

**The above list includes some side effects of your medicine. They are usually mild and short lived.**

**Tell your doctor immediately if you notice any of the following:**

- Dizziness, lightheadedness (low blood pressure)
- Dizziness on standing up, especially when getting up from a sitting or lying position
- Fainting
- Upper respiratory tract infection such as sore throat, discomfort when swallowing or inflammation of the sinuses
- Urinary tract infection including inflammation of bladder. The symptoms includes painful and frequent urination, need to urinate at night.
- Abnormal liver function and liver disorder
- Kidney impairment or kidney disease where you pass little or no urine
- Pale skin and weakness or breathlessness
- Bleeding or bruising more easily than normal

**The above list includes serious side effects that may require medical attention.**

**If any of the following happens, tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:**

- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Painful red areas, large blisters on skin, peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.
- Drug eruption
- Sepsis (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death),

**The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.**

#### **Laboratory test**

There may be changes in the results of certain laboratory tests:

- Increase blood levels of creatinine
- Increase serum potassium levels
- Increase blood levels of creatine phosphokinase and uric acid
- Increase in liver enzymes
- Decrease blood levels of haemoglobin
- Increase in white blood cells (eosinophilia)

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

## **After using TELEACT TABLETS**

### **Storage**

Store below 30°C. Protect from moisture

### **Disposal**

**Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.**

## **Product description**

### **What TELEACT TABLETS looks like**

For 40 mg strength: Off-white to light yellow coloured, oblong tablets, debossed with 'T12' on one side and plain on the other side

For 80 mg strength: Off-white to light yellow coloured, oblong tablets, debossed with 'T13' on one side and plain on the other side

## **Ingredients**

### **Active ingredient:**

**Telmisartan Ph. Eur**

Eq. to **Telmisartan**

### **Inactive ingredients:**

**TELEACT 40/80 mg Tablets contains:**

Sorbitol

Magnesium stearate

### **Reg. No.**

**40mg: MAL13015031AZ**

**80mg: MAL13015032AZ**

## **Manufacturer and Product Registration Holder**

RANBAXY (MALAYSIA) SDN. BHD.  
Lot 23, Bakar Arang Industrial Estate,  
08000 Sungai Petani, Kedah,  
Malaysia.

### **Date of Preparation:**

**24- Jun-2019**

Serial No.: NPRA(R2/1)190624/175