

**Package leaflet: Information for the user**  
**PATIENT INFORMATION LEAFLET (PIL)**  
**FOR**  
**SAFETELMI 20/40/80 (TELMISARTAN TABLETS USP 20 mg/40 mg/80 mg)**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**

1. What Safetelmi is and what it is used for
2. What you need to know before you take Safetelmi
3. How to take Safetelmi
4. Possible side effects
5. How to store Safetelmi
6. Contents of the pack and other information

**1. What is Safetelmi and what it is used for?**

Safetelmi 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. Safetelmi blocks the effect of angiotensin II so that the blood vessels relax and your blood pressure is lowered. **Safetelmi is used to treat** essential hypertension (high blood pressure) in adults. ‘Essential’ means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Safetelmi is also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

**2. What you need to know before you take Safetelmi?**

**Do not take Safetelmi**

- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid Safetelmi in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Safetelmi.

## **Warnings and precautions**

Talk to your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- 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.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Safetelmi is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Safetelmi.

Safetelmi may be less effective in lowering the blood pressure in black patients.

## **Children and adolescents**

The use of Safetelmi in children and adolescents up to the age of 18 years is not recommended.

## **Other medicines and Safetelmi**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 Safetelmi:

- 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, immuno suppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Safetelmi, may lead to excessive loss of body water and low blood pressure (hypotension).

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

Safetelmi may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

## **Pregnancy and breast-feeding**

### ***Pregnancy***

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Safetelmi before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Safetelmi. Safetelmi is 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.

### **Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Safetelmi is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is new born, or was born prematurely.

### **Driving and using machines**

Some people feel dizzy or tired when taking Safetelmi. If you feel dizzy or tired, do not drive or operate machinery.

### **Safetelmi contains sorbitol.**

If you are intolerant to some sugars, consult your doctor before taking Safetelmi.

### **3. How to take Safetelmi**

Always take Safetelmi exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Safetelmi is one tablet a day. Try to take the tablet at the same time each day.

You can take Safetelmi with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Safetelmi every day until your doctor tells you otherwise. If you have the impression that the effect of Safetelmi is too strong or too weak, talk to your doctor or pharmacist.

For treatment of high blood pressure, the usual dose of Safetelmi for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Safetelmi may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Safetelmi.

For reduction of cardiovascular events, the usual dose of Safetelmi is one 80 mg tablet once a day. At the beginning of the preventive therapy with Safetelmi 80 mg, blood pressure should be frequently monitored. If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

### **If you take more Safetelmi than you should**

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

### **If you forget to take Safetelmi**

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Some side effects can be serious and need immediate medical attention:**

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis\* (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal.

#### **Possible side effects of Safetelmi:**

Common side effects (may affect up to 1 in 10 people):

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

**Uncommon side effects** (may affect up to 1 in 100 people):

Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

**Rare side effects** (may affect up to 1 in 1,000 people):

Sepsis\* (often called “blood poisoning”, is a severe infection with whole-body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), feeling anxious, somnolence, impaired vision, fast heart beat (tachycardia), dry mouth, upset stomach, abnormal liver function (Japanese patients are more likely to experience these side effect), rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), eczema (a skin disorder), redness of skin, hives (urticaria), severe drug rash, joint pain (arthralgia), pain in extremity, tendon pain, flu-like-illness, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

**Very rare side effects** (may affect up to 1 in 10,000 people):

Progressive scarring of lung tissue (interstitial lung disease)\*\*.

\*The event may have happened by chance or could be related to a mechanism currently not known.

\*\*Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

## **5. How to store Safetelmi**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month. This medicine does not require any special temperature storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Shelf Life:** 36 M

## **6. Contents of the pack and other information**

### **What Safetelmi contains**

The active substance is Telmisartan USP. Each tablet contains Telmisartan USP 20/40/80 mg and the excipients are Microcrystalline cellulose, croscarmellose sodium, meglumine, poloxamer 188 NF, povidone, isopropyl alcohol & magnesium stearate.

**What Safetelmi looks like and contents of the pack**

White to off white colored round shaped smooth flat bevel edged plain both sides uncoated tablet.  
10 tablets of Telmisartan Tablets USP 20 mg/40 mg/80 mg are packed in Aluminium base foil (288 mm) on one side and Aluminium lidding foil (288 mm) on another side in the form of Aluminium-Aluminium blister pack and such 1 or 3 packs are further packed in pre-printed carton along with instructions for use.

**Marketing Authorisation Holder**

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