

# TEVETEN 600MG TABLET

Eprosartan 600mg

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### 1. What TEVETEN is used for

Teveten is used to treat high blood pressure.

### 2. How TEVETEN works

Teveten contains the active ingredient eprosartan. Eprosartan belongs to a group of medicines called 'angiotensin II receptor antagonists'. It blocks the action of a substance in your body called 'angiotensin II'. This substance causes your blood vessels to narrow. This makes it more difficult for the blood to flow through the vessels and so your blood pressure increases. By blocking this substance, the vessels relax and your blood pressure decreases.

### 3. Before you use TEVETEN

#### When you must not use it

Do not take Teveten if:

- you are allergic (hypersensitive) to eprosartan or any of the other ingredients in Teveten (listed in Section 8)
- you have **severe** problems with the blood flow in your kidneys
- you are more than 3 months pregnant (it is also better to avoid Teveten in early pregnancy – see pregnancy section).

Do not take Teveten if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

#### Before you start to use it

Check with your doctor or pharmacist before taking this medicine if:

- you have any liver problems
- you have any other kidney problems. Your doctor will check how well your kidneys are working before you start your treatment and at intervals during your treatment. Your doctor will also check the potassium, 'creatinine' and 'uric acid' levels in your blood
- you have a heart problem such as coronary heart disease, heart failure, a narrowing of your blood vessels or heart valves, or a problem with your heart muscle
- you produce too much of a hormone called 'aldosterone'
- you are on a low-salt diet, taking 'water tablets' or are being sick or have diarrhoea. This is because they may cause your blood volume or the sodium level in your blood to decrease. These should be corrected before starting treatment with Teveten
- you think you are (or might become) pregnant. Teveten 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.

- If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Teveten.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Teveten can affect the way some other medicines work. Also some other medicines can affect the way Teveten works.

#### **In particular, tell your doctor or pharmacist if you are taking the following:**

- lithium – for mood problems. Your doctor must monitor the lithium level in your blood because Teveten may increase the level.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Teveten.

#### **The following medicines may increase the effect of Teveten:**

- medicines that lower your blood pressure.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Teveten.

Talk to your doctor or pharmacist before taking Teveten.

Depending on the outcome of your blood tests, your doctor may decide to change your treatment with these medicines or Teveten.

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## 4. How to use TEVETEN

### How much to use

#### **Adults**

The usual dose is one tablet a day.

#### **Children and adolescents**

Teveten should not be given to children and adolescents under 18 years.

### When to use it

Take the tablets in the morning at around the same time each day.

### How long to use it

Do not stop taking Teveten without talking to your doctor first

### If you forget to take it

If you forget a dose, take it as soon as you remember it.

If you forget to take a dose and it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose

### If you take too much (overdose)

If you take more Teveten than you should or someone accidentally takes some, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects can happen:

- feeling light-headed and dizzy due to a fall in your blood pressure (hypotension)

## 5. While you are using TEVETEN

### Things you must do

#### Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Teveten before you become pregnant or as soon as you know you are pregnant and

will advise you to take another medicine instead of Teveten.

Teveten is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant. 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.

Teveten is not recommended for mothers who are breast-feeding. Your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant, might become pregnant or are breast-feeding.

### Things you must not do

#### **Driving and using machines**

Teveten is unlikely to affect your ability to drive or use tools and machines. However, you may feel sleepy or dizzy while taking Teveten. If this happens, do not drive or use any tools or machines and talk to your doctor.

### Things to be careful of

Teveten contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine. take Trade

Always take Teveten exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

## 6. Side effects

Like all medicines, Teveten can cause side effects, although not

everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (affect less than 1 in 100 people)

If you have an allergic reaction, stop taking and see a doctor straight away. The signs may include:

- skin reactions such as a rash or hives with swelling (urticaria)
- swelling of the lips, face, throat or tongue
- shortness of breath
- swelling of your face, swelling of skin and mucous membrane (angioedema).

Other possible side effects of Teveten include:

Very common (affects more than 1 in 10 people)

- headache.

Common (affects less than 1 in 10 people)

- feeling dizzy
- a rash or itch (pruritus)
- feeling sick, being sick, diarrhoea
- feeling weak (asthenia)

Uncommon (affects less than 1 in 100 people)

- low blood pressure, including low blood pressure when standing up. You may feel light-headed or dizzy.

Frequency not known

- kidney problems, including kidney failure.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers - Reporting)

## 7. Storage and Disposal of TEVETEN

### Storage

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Teveten after the 'use before' date (expiry date) which is stated on the carton and blister.

The 'use before' date refers to the last day of that month.

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 8. Product Description

### What it looks like

Teveten 600 mg:

Capsule-shaped white film-coated tablet marked '5046' on one side and 'SOLVAY' on the other side.

Teveten 600 mg is provided in blisters containing 14, 28, 56 or 98 tablets.

Not all pack sizes may be marketed.

### Ingredients

The active ingredient is eprosartan (as mesylate) equivalent to 600 mg eprosartan per tablet.

The other ingredients are:  
Lactose monohydrate,  
microcrystalline cellulose,

pregelatinised starch,  
crospovidone magnesium stearate, purified water, hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433)

### MAL Number

MAL06081194A

## 9. Manufacturer and Product Registration Holder

### Manufacturer

Abbott Biologicas B.V  
Veerweg 12,  
The Netherlands

### Product Registration Holder

ABBOTT LABORATORIES  
(M) SDN. BHD.  
No.22, Jalan Pemaju U1/15,  
Seksyen U1,  
HICOM-Glenmarie Industrial  
Park,  
40150 Shah Alam, Selangor  
Darul Ehsan,  
MALAYSIA.

## 10. Date of Revision

29/01/2014