

PACKAGE LEAFLET

Package leaflet: Information for the User

Teveten 300 mg and 600 mg Film-coated Tablets

Eprosartan

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Teveten is and what it is used for
2. Before you take Teveten
3. How to take Teveten
4. Possible side effects
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1. What Teveten is and what it is used for

What Teveten is used for

Teveten contains a medicine called eprosartan mesilate. This belongs to a group of medicines called 'angiotensin II receptor antagonists'.

This medicine is used to treat high blood pressure, also called hypertension.

The main cause of high blood pressure is narrowing of the blood vessels. This increases the amount of work your heart must do to pump blood around your body. You may not feel unwell, but, if high blood pressure is not treated, it can lead to heart disease and stroke.

How Teveten works

- Angiotensin II is a chemical found in the body which makes your blood vessels contract. This makes it more difficult for blood to pass through them
- This causes your blood pressure to rise
- Teveten works by preventing the chemical, angiotensin II, from causing your blood vessels to contract. This has the effect of lowering your blood pressure.

You may be given Teveten on its own or with another medicine used to treat high blood pressure. Using both medicines together will lower your blood pressure more than one on its own.

The active ingredient in this medicine is eprosartan mesilate. This is the new name for eprosartan mesylate. The active ingredient itself has not changed.
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2. Before you take Teveten

Do not take Teveten if:

- You are allergic (hypersensitive) to eprosartan or any of the other ingredients of Teveten (listed in section 6 below)
- You have severe liver problems
- You are more than 3 months pregnant (it is also better to avoid Teveten in early pregnancy – see pregnancy section)
- You have damaged blood flow to the kidneys or serious constrictions in a single functioning kidney
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

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 Teveten.

Take special care with Teveten

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

- You have heart, kidney or liver problems, especially severe heart failure, narrowing of the heart valves, thickening of heart muscle (hypertrophic cardiomyopathy)
- You have narrowing or a blockage of the blood vessels leading to your kidneys or if you only have one kidney
- You have recently been sick or had diarrhoea
- You are taking water tablets (diuretics) and they make you feel dizzy when you stand up
- You are taking water tablets or potassium supplements and you also have a kidney problem. Your doctor might sometimes check your blood to make sure that Teveten is not affecting the amount of potassium in your blood
- You are taking other medicines that may increase serum potassium (see section “Taking other medicines”)
- You suffer from lactose intolerance (see section ‘Important information about some of the ingredients of 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)
- You have been told you have Conn’s syndrome (primary hyperaldosteronism) i.e. your body is making too much of the hormone aldosterone. Teveten may not work so check with your doctor.
- You are taking medicines to treat high blood pressure such as aliskiren or an ACE-inhibitor (for example enalapril, lisinopril, Ramipril), particularly if you have diabetes-related kidney problems. Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Teveten. See also Section 2 of this leaflet under the heading “Do not take Teveten”.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Teveten. Your doctor will decide on further treatment. Do not stop taking Teveten on your own.

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. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for pain and inflammation such as ibuprofen, diclofenac, celecoxib, etoricoxib or lumiracoxib (Non-steroidal anti-inflammatory medicines)

- Potassium supplements, potassium-sparing agents or potassium-containing salt substitutes
- Medicines that increase potassium levels such as heparin and trimethoprim
- Water tablets (Diuretics) such as hydrochlorothiazide and calcium channel blocker such as nifedipine, which may be used to help lower your blood pressure
- Aspirin used for pain, fever and to prevent blood clotting
- Lithium used for mental problems
- ACE inhibitors or aliskiren (See also Section 2 of this leaflet under the headings “Do not take Teveten” and “Take special care with Teveten”)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Teveten.

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 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, 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. Teveten 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 newborn, or was born prematurely.

Driving and using machines

You may feel tired or dizzy when you start taking Teveten. If this happens, do not drive or use any tools or machines until these effects wear off.

Important information about some of the ingredients of Teveten

Teveten 300 mg and 600 mg film-coated tablets contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

Teveten 300 mg: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Teveten

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

Taking this medicine

- Your doctor will tell you how many tablets to take and for how long. It is important that you keep taking the tablets for as long as your doctor tells you
- The pharmacist’s label on your pack will also tell you how much your doctor would like you to take. Please read it carefully
- Only remove a tablet from the blister strip when it is time to take your medicine
- Take your tablet with or without food
- Take your tablets at about the same time each day

Adults aged under 75 years

- The usual dose is 600 mg once a day

Elderly people (aged 75 or over) and people with kidney or liver problems

- No dose adjustment is required in elderly people.

- If you have liver or kidney problems, consult your doctor. Your doctor will decide your daily dosage.

Children and adolescents

Teveten should not be used in children and adolescents under 18 years.

If you take more Teveten than you should

If you take more Teveten than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Teveten

- If you forget to take a dose, take it as soon as you remember
- Take your next dose at the normal time
- Do not take two doses within 12 hours of each other.

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

4. Possible side effects

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

Stop taking Teveten and see a doctor straight away if you develop any of the following symptoms – you may need urgent medical treatment:

- Sudden swelling of your face, lips or tongue and breathing problems. These may be signs of a severe allergic reaction and may be life-threatening. This side effect is uncommon (at least 1 in 1000 and less than 1 in 100 patients).

A list of possible side effects reported in clinical studies with Teveten is given below:

Very common (at least 1 in 10 patients or more)

- Headache

Common (at least 1 in 100 and less than 1 in 10 patients)

- Skin rashes or itching
- Weakness or lack of strength
- Feeling dizzy
- Feeling or being sick (nausea or vomiting)
- Diarrhoea
- Runny nose

Uncommon (at least 1 in 1000 and less than 1 in 100 patients)

- Low blood pressure (hypotension)
- Sudden swelling of your face, lips or tongue and breathing problems. These may be signs of a severe allergic reactions and may be life threatening.

Undesirable effects have been reported since Teveten has been marketed but the frequency is not known

- Changes in kidney function including kidney failure in patients with existing kidney problems.
- Pain in a joint
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Teveten

- Keep this medicine out of the sight and reach of children.
- You should lock this medicine in a cupboard or medicine cabinet
- Do not use the tablets after the expiry date which is printed on the carton and blister pack
- Do not store your tablets above 25°C. Keep them in the original container.

If your doctor stops your treatment, return any unused tablets to a pharmacist. 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 protect the environment.

6. Further Information

What Teveten contains

- The active substance is eprosartan (as mesilate). Each tablet contains 300 mg or 600 mg of eprosartan.
- The other ingredients are: lactose, microcrystalline cellulose (E460), pregelatinised starch, magnesium stearate (E572), hypromellose, titanium dioxide (E171), polysorbate 80 (E433) and macrogol 400
- The 300 mg tablets also contain croscarmellose sodium
- The 600 mg tablets also contain crospovidone.

What Teveten looks like and contents of the pack

Teveten 300 mg Film-coated Tablets are white and oval-shaped with the marking 5043.

Teveten 600 mg Film-coated Tablets are white and capsule-shaped with the marking 5046.

Teveten is available in blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Mylan Products Ltd.,
20 Station Close,
Potters Bar,
Herts, EN6 1TL, UK

The Manufacturer is:

Mylan Laboratories SAS,
F-01400 Chatillon-sur-Chalaronne,
France.

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For more information on blood pressure, you may find the following organisation helpful:

The Blood Pressure Association

60 Cranmer Terrace

London SW17 0QS

Phone: 020 8772 4994

Website: www.bpassoc.org.uk