PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Teveten 400 mg and Teveten 600 mg, film-coated tablets
Eprosartan

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. See section 4.

What is in this leaflet

1. What Teveten is and what it is used for

Teveten is used:
- to treat high blood pressure.

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.

2. What you need to know before you take Teveten

Do not take Teveten if:
- you are allergic (hypersensitive) to eprosartan or any of the other ingredients in Teveten (listed in Section 6)
- you have **severe** liver disease
- you have **severe** problems with the blood flow in your kidneys
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if:
- you have any other 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 check the potassium, 'creatinine' and 'uric acid' levels in your blood
- you are taking any of the following medicines used to treat high blood pressure:
    - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
    - aliskiren

  Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading "Do not take Teveten"
- 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.

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

Other medicines and Teveten

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.
- Non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, naproxen, diclofenac, indometacin, acetylsalicylic acid, celecoxib or etoricoxib - medicines to relieve pain and inflammation

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

Your doctor may need to change your dose and/or to take other precautions:
If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Teveten" and "Warnings and precautions").

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.

If you are taking any of the following medicines your doctor may carry out blood tests:

- medicines containing potassium or potassium-sparing medicines
- medicines that increase potassium levels such as 'heparin' and 'ACE inhibitors'.

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.

Taking Teveten with food, drink and alcohol

- You can take the tablets with or without food.
- Speak to your doctor before taking Teveten if you are on a low-salt diet. Not having enough salt may cause your blood volume or the sodium level in your blood to get lower.

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. 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.

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.

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.

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

- Take this medicine by mouth.
- Swallow the tablet whole with plenty of fluid such as a glass of water.
- Do not crush or chew the tablets.
- Take the tablets in the morning at around the same time each day.

How much to take

Adults

The usual dose is one tablet a day.

Use in children and adolescents

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

If you take more Teveten than you should

If you take more Teveten than you should or someone accidently 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)
- feeling sick (nausea)
- feeling sleepy.

If you forget to take Teveten

- 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 stop taking Teveten

Do not stop taking Teveten without talking to your doctor first.

4. Possible 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 (angiodema).

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)
- stuffy nose (rhinitis).

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.
- joint pain (arthralgia)

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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Teveten

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.

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.

6. Contents of the pack and other information

What Teveten contains

The active ingredient is eprosartan (as mesylate) equivalent to 400 mg or 600 mg eprosartan per tablet.

The other ingredients are:

- Tablet core of Teveten 400 mg: lactose monohydrate, microcrystalline cellulose, pregelatinized starch (from maize), croscarmellose sodium, magnesium stearate, purified water.
- Tablet core of Teveten 600 mg: lactose monohydrate, microcrystalline cellulose, pregelatinized starch (from maize), crospovidone, magnesium stearate, purified water.
- Film coat of Teveten 400 mg: hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), iron oxide yellow (E172), iron oxide red (E172).
- Film coat of Teveten 600 mg: hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433).

What Teveten looks like and contents of the pack

Teveten 400 mg:
Oval, light to moderately pink film-coated tablet marked '5044' on one side.

Teveten 600 mg:
Capsule-shaped white film-coated tablet marked '5046' on one side.

Teveten 400 mg and Teveten 600 mg are provided in blisters containing 14, 28, 56, 98 or 280 (10 x 28) film-coated tablets.
Teveten 400 mg is also available in blister packs of 4, 7 and 50 (5 x 10) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mylan IRE Healthcare Limited,
Unit 35/36,
Grange Parade,
Baldoyle Industrial Estate,
Dublin 13.

Manufacturer:

Teveten 400 mg:
Mylan Laboratories SAS
Route de Belleville, Lieu dit Maillard
F-01400 Châtillon-sur-Chalaronne
Tel.: +33 4 74 45 54 42
Fax: +33 4 74 55 02 83

Teveten Mono 600 mg:
Mylan Laboratories SAS
Route de Belleville, Lieu dit Maillard
F-01400 Châtillon-sur-Chalaronne
Tel.: +33 4 74 45 54 42
Fax: +33 4 74 55 02 83

Teveten 400 mg is authorised in the Member States of the EEA under the following names:

Germany, Ireland	Teveten 400 mg
Italy	TevetenZ 400 mg

Teveten 600 mg is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Finland, Greece, Ireland, Luxembourg, Portugal, Sweden	Teveten 600 mg
Germany	Teveten Mono 600 mg
Italy	TevetenZ 600 mg

This leaflet was last revised in 04/2018