Package leaflet: Information for the user

Teveten® Plus 600 mg/12.5 mg film-coated tablets

eprosartan/hydrochlorothiazide

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.

The full name of your medicine is Teveten Plus 600 mg/12.5 mg film-coated tablets. In this leaflet the shorter name Teveten Plus is used.

What is in this leaflet

1. What Teveten Plus is and what it is used for

Teveten Plus is used:
- to treat high blood pressure.

Teveten Plus contains two active ingredients: eprosartan and hydrochlorothiazide.
- **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.
- **hydrochlorothiazide** belongs to a group of medicines called “thiazide diuretics”. It increases how often and how much urine you pass. This decreases your blood pressure.

You will only be given Teveten Plus if your blood pressure is not lowered enough by eprosartan on its own.

2. What you need to know before you take Teveten Plus

Do not take Teveten Plus if:
- you are allergic to eprosartan, hydrochlorothiazide or any of the other ingredients of this medicine (listed in Section 6).
- you are allergic to a group of medicines called ‘sulfonamides’
- you have **severe** liver disease
- you have **severe** kidney 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 have high calcium, low potassium or low sodium levels. These are all things that can be measured in your blood
- you have a problem with your gall bladder or bile duct (gallstones)
- you have gout or other signs of a raised “uric acid” level in your blood (hyperuricaemia)
- you are more than 3 months pregnant (it is also better to avoid Teveten Plus in early pregnancy – see pregnancy section).

Do not take Teveten Plus 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 Teveten Plus if:
- you have any other liver problem
- you have had a kidney transplant
- 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 Plus”
- 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 have a condition called ‘Systemic Lupus Erythematosus’ (SLE)
- you have diabetes. Your doctor may need to alter the dose of your diabetic medicines
- you produce too much of a hormone called “aldosterone”
- you have a history of any allergies
- you are on a low-salt diet, taking ‘water tablets’ (diuretics) 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 Plus
- you are taking other medicines that may increase serum potassium (see section “Other medicines and Teveten Plus”).
- you think you are (or might become) pregnant. Teveten Plus 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 had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Teveten Plus.
- you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Teveten Plus. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Teveten Plus, seek medical attention immediately.

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

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Your doctor may check the electrolytes in your blood regularly.

Operations and tests

Talk to your doctor or pharmacist before taking this medicine if you are due to have the following:
- an operation or surgery
- an anti-doping test. The hydrochlorothiazide in this medicine may lead to a positive result
- any other blood tests.

Other medicines and Teveten Plus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Teveten Plus can affect the way some other medicines work. Also some other medicines can affect the way Teveten Plus 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 Plus may increase the level
- medicines for diabetes such as metformin or insulin. Your doctor may need to alter the dose of your diabetic medicines
- medicines which can cause potassium loss. These include ‘water tablets’, ‘laxatives’, ‘corticosteroids’, amphotericin (an anti-fungal medicine), carbenoxolone (treatment of mouth ulcers) and a hormone produced by the pituitary gland called ‘ACTH’. Teveten Plus may increase the risk of low blood potassium levels when taken with these medicines
- medicines which can reduce the amount of sodium in your blood. These include medicines to treat depression, psychosis and epilepsy. Teveten Plus may increase the risk of low blood sodium levels when taken with these medicines
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, naproxen, diclofenac, indometacin, acetylsalicylic acid, celecoxib or etoricoxib – medicines to relieve pain and inflammation
- digitalis glycosides such as digoxin used for heart failure or a fast and irregular heartbeat. Teveten Plus may increase the risk for irregular heart beat
- beta-blockers and diazoxide. When taken with Teveten Plus the sugar level in your blood may increase
- medicines to treat cancer such as ‘methotrexate’ and ‘cyclophosphamide’
- medicines that tighten your blood vessels or stimulate your heart, such as noradrenaline
- medicines which relax your muscles such as ‘baclofen’ and ‘tubocurarin’
- anaesthetics
- amantadine used to treat Parkinson’s disease or viral diseases. Teveten Plus may increase the risk of side effects caused by amantadine.

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

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 Plus” and “Warnings and precautions”).

The following medicines may decrease the effect of Teveten Plus
- medicines which decrease fat in your blood such as ‘colestipol’ and ‘cholestyramine’.

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

The following medicines may increase the effect of Teveten Plus
- sleep-inducing medicines such as ‘sedatives’ and ‘narcotics’
- medicines to treat depression
- some medicines for Parkinson’s disease such as ‘biperiden’
- medicines that lower your blood pressure
- ‘amifostine’ a medicine which protects cells from chemotherapy

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

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’, ‘trimethoprim and ‘ACE inhibitors’
- medicines for gout such as ‘probenecid’, ‘sulfinpyrazone’ and ‘allopurinol’
- medicines for diabetes such as ‘metformin’ and ‘insulin’
- medicines to control the rhythm of your heart such as quinidine, disopyramide, amiodarone and sotalol
- some antibiotics such as ‘tetracyclines’
- some antipsychotic medicines such as thioridazine, chlorpromazine and levopromazine
- calcium salts or Vitamin D
- steroids.

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

Teveten Plus with food, drink and alcohol
- Drinking alcohol while taking Teveten Plus can reduce your blood pressure and you may feel tired or dizzy.
- Speak to your doctor before taking Teveten Plus 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 Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Teveten Plus.
- Teveten Plus 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 Plus 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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Teveten Plus contains lactose
Teveten Plus contains lactose (a type of sugar). If you have been told by your doctor that have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Teveten Plus

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

Taking this medicine
- Take this medicine by mouth.
- You can take the tablets with or without food.
- 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 Plus should not be given to children and adolescents under 18 years.

If you take more Teveten Plus than you should
If you take more Teveten Plus 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
- feeling thirsty (dehydration).

If you forget to take Teveten Plus
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 Plus
Do not stop taking Teveten Plus without talking to your doctor first.
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. The following side effects may happen with this medicine:

Allergic reactions
If you have an allergic reaction, stop taking Teveten Plus and see a doctor straight away. The signs may include:
- skin reactions such as a rash or hives with swelling (urticaria), (may affect up to 1 in 10 people)
- swelling of your face, swelling of skin and mucous membrane (angioedema), (may affect up to 1 in 100 people)

Other possible side effects of Teveten Plus include:
Very common (may affect more than 1 in 10 people)
- headache

Common (may affect up to 1 in 10 people)
- feeling dizzy
- pins and needles, nerve pain
- feeling sick, being sick or diarrhoea
- feeling weak (asthenia)
- rash
- itching
- stuffy nose (rhinitis)
- low blood pressure, including low blood pressure when standing up. You may feel light-headed or dizzy.
- changes in blood tests such as increased blood level of glucose (hyperglycaemia)

Uncommon (may affect up to 1 in 100 people)
- trouble sleeping (insomnia)
- feeling depressed
- feeling anxious or nervous
- sexual dysfunction and/or change of sexual desire
- muscle cramps
- fever
- dizziness (vertigo)
- constipation,
- changes in blood tests such as:
  - increased level of uric acid (gout)
  - increase in fat (cholesterol,)
  - decreased potassium, sodium and chloride levels
  - decreased number of white blood cells

Rare (may affect up to 1 in 1,000 people)
- water in the lungs
- inflammation of the lungs,
- inflammation of the pancreas

Very rare (may affect less than 1 in 10,000 people)
- haemolytic anaemia
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

Not known (frequency cannot be estimated from the available data)
Lack of appetite, jaundice, visual disturbances or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma), feeling restless, changes in blood count: decrease granulocytes and platelets, disturbance of red blood cell formation; decreased level magnesium in the blood, increased level of calcium and triglycerides in the blood, renal disorders, inflammation of the kidney, acute renal failure, inflammation of blood vessel wall, formation of skin bubbles incl. dead skin cells (toxic epidermal necrolysis), rash/skin lesions usually on sun-exposed areas due to an autoimmune disease (cutaneous lupus erythematosus), systemic lupus erythematosus, joint pain (arthralgia), severe allergic reactions (anaphylactic reactions), increased sensitivity to (sun)light (photosensitivity), skin and lip cancer (non-melanoma skin cancer).

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, Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Teveten Plus

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 and blister after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Teveten Plus contains
The active substances are eprosartan and hydrochlorothiazide. Each film-coated tablet contains 600 mg eprosartan (as mesylate) and 12.5 mg hydrochlorothiazide.

The other ingredients are:
- Tablet core: lactose monohydrate, microcrystalline cellulose, pregelatinised starch (from maize), crospovidone, magnesium stearate, purified water.
- Film coat: polyvinyl alcohol, talc, titanium dioxide (E171), macrogol 3350, iron oxide yellow (E172), iron oxide black (E172).

What Teveten Plus looks like and contents of the pack
Butterscotch-coloured, capsule-shaped film-coated tablets.
They are marked 5147 on one side of the tablet.
Teveten Plus is provided in blisters containing 28 tablets.

On the Greek blister weekday abbreviations appear on the blister foil. Here is a translation of the weekdays in English and Greek:

English	Greek
Monday	ΔΕΥ
Tuesday	ΤΡΙ
Wednesday	ΤΕΤ
Thursday	ΠΕΜ
Friday	ΠΑΡ
Saturday	ΣΑΒ
Sunday	ΚΥΡ

Manufacturer
Mylan Laboratories SAS, Route de Belleville, Lieu dit Maillard, F- 01400 Châtillon-sur-Chalaronne, France.

Parallel Product Authorisation number:
Teveten Plus 600 mg/12.5 mg – PPA 465/448/1

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Teveten is a registered trademark of BGP Products Operations GmbH.

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

Germany	Teveten Plus HCT 600 mg/12.5 mg
Belgium, Greece, Ireland, Luxembourg, Portugal	Teveten Plus 600 mg/12.5 mg

Finland, Norway, Sweden	Teveten Comp 600 mg/12.5 mg
Italy	Tiartan
Spain	Tevetens Plus 600 mg/12.5 mg
Austria	Teveten Plus

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