

TEVETEN® PLUS

eprosartan mesilate and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Teveten Plus. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Teveten Plus against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Teveten Plus is used for

Teveten Plus lowers high blood pressure, which doctors call hypertension.

There are usually no symptoms of hypertension. The only way to know if you have high blood pressure is to have your blood pressure checked regularly.

If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Teveten Plus contains two active ingredients, eprosartan and hydrochlorothiazide, both of which act in different ways to lower your blood pressure.

Eprosartan belongs to a group of medicines called angiotensin-II receptor antagonists. Eprosartan

works by blocking the action of a substance called angiotensin-II, helping to relax the blood vessels and lower your blood pressure.

Hydrochlorothiazide belongs to a group of medicines known as diuretics, or water (fluid) tablets. It works by making your kidneys pass more water and salt. This helps reduce high blood pressure and some forms of swelling.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another use.

There is no evidence that this medicine is addictive.

Teveten Plus is only available with a doctor's prescription.

Teveten Plus is not recommended for use in children.

The safety and effectiveness of this medicine in children has not been established.

Before you take Teveten Plus

When you must not take it

Do not take Teveten Plus if you have an allergy to:

- any medicine containing eprosartan or hydrochlorothiazide
- any medicine containing sulfonamides
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant or think you may be pregnant.

Do not breast-feed if you are taking this medicine.

Do not take Teveten Plus if:

- you have severe liver or kidney problems
- you have had any problems with your gall bladder or bile duct
- you have gout
- you have diabetes and are taking an aliskiren medicine (another medicine used to treat high blood pressure)
- you have electrolyte disturbances

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have had any of the following medical conditions:

- liver or kidney problems
- heart problems
- diabetes
- gout

- lupus erythematosus, a skin and tissue disease
- primary hyperaldosteronism
- excessive vomiting or diarrhoea recently

Tell your doctor if you are or have been taking diuretics (water/fluid) tablets.

Tell your doctor if you are on a salt restricted diet.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have changes in your vision or pain in one or both of your eyes while taking Teveten Plus.

These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or sign that you are developing glaucoma or increased pressure in your eye(s) and can happen within hours to weeks of taking Teveten Plus. You should stop taking this medicine and seek medical attention.

If you have not told your doctor about any of the above, tell them before you start taking Teveten Plus.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Teveten Plus may interfere with each other. These include but are not limited to:

- other high blood pressure medicines, especially ACE inhibitors, medicines that contain aliskiren, or diuretics (water or (fluid tablets)
- medicines affecting potassium levels
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines

used to relieve pain, swelling and other symptoms of inflammation

- diabetes medication
- heart medication
- gout medication
- muscle relaxants
- medications used to treat psychiatric conditions, and epilepsy.
- Parkinson's medication
- laxatives, corticosteroids and adrenocorticotrophic hormone (ACTH)
- cancer medication
- calcium and vitamin D supplements

These medicines may be affected by Teveten Plus or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Teveten Plus

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablet(s) to take each day.

The usual dose of Teveten Plus is one (1) tablet per day.

How to take it

Swallow the tablet whole with a glass of water.

Do not chew the tablet.

You may take Teveten Plus with or without food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Teveten Plus helps control your high blood pressure, but does not cure it. It is important to keep taking your medicine even if you feel well.

You may need to take this medicine for the rest of your life.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Teveten Plus.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Teveten Plus.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery (including at the dentist), tell the surgeon, dentist or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Make sure you drink enough water during exercise and hot weather when you are taking Teveten Plus, especially if you sweat a lot.

If you feel faint or light-headed during exercise or hot weather, speak to your doctor.

Tell your doctor if you have experienced excessive vomiting and/or diarrhoea while taking this medicine.

If you have had skin cancer or if you develop a suspicious skin lesion during treatment with Teveten Plus, tell your doctor immediately.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin (non-melanoma) cancer. Limit exposure to sunlight and protect your skin when exposed to sun while taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Teveten Plus to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Teveten Plus affects you.

Many medicines used to treat high blood pressure may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Teveten Plus.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- headache
- tiredness, fatigue or weakness
- trouble sleeping
- diarrhoea, feeling sick (nausea) or vomiting
- stomach pain or discomfort
- joint pain
- urinary tract infection

- cough

These are common side effects of Teveten Plus and usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- if you are on diabetic medication and you feel excessive thirst, nausea, vomiting or generally unwell
- muscle aches and pains
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and eyes, also called jaundice
- numbness or tingling in the hands or feet
- skin rash, itchiness

These side effects may require medical attention. These side effects are rare.

Tell your doctor immediately if you notice any of the following:

- severe skin reactions
- hives or itching
- reddening of the skin
- not passing urine or not passing as much urine as usual, a burning sensation or evidence of blood
- eye pain or blurred vision
- chest pain

These are serious side effects which may require urgent medical attention or hospitalisation. These side effects are very rare.

If any of the following happens, stop taking Teveten Plus and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of limbs, face, eyes, inside the nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- unusual tiredness or weakness that is sudden and severe
- fainting within a few hours of taking this medicine

These are very serious side effects and may indicate a severe allergic reaction. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Teveten Plus or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can damage some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is leftover.

Product description

What it looks like

Butterscotch coloured, capsule shaped tablet marked "5147" on one side.

Teveten Plus is available in packs of 7 (starter pack) or 28 tablets.

Ingredients

Active ingredients:

Each tablet contains 600 mg eprosartan (as eprosartan mesilate) and 12.5 mg hydrochlorothiazide.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- microcrystalline cellulose
- pregelatinized maize starch
- crospovidone
- magnesium stearate
- Opadry 85F27320

Teveten Plus does not contain sucrose, tartrazine or any other azo dyes.

Sponsor

Teveten Plus is supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
www.mylan.com.au
Phone: 1800 314 527

This leaflet was prepared in Oct 2020.

Australian Registration Number:

AUST R 143172

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