

TEVETEN® PLUS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TEVETEN PLUS?

TEVETEN PLUS contains the active ingredients eprosartan and hydrochlorothiazide. TEVETEN PLUS is used to lower high blood pressure which doctors call hypertension.

For more information, see Section [1. Why am I using TEVETEN PLUS?](#) in the full CMI.

2. What should I know before I use TEVETEN PLUS?

Do not use if you have ever had an allergic reaction to eprosartan, hydrochlorothiazide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TEVETEN PLUS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TEVETEN PLUS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TEVETEN PLUS?

- Your doctor will decide what dose you should receive.
- The usual dose of TEVETEN PLUS is one tablet per day.

More instructions can be found in Section [4. How do I use TEVETEN PLUS?](#) in the full CMI.

5. What should I know while using TEVETEN PLUS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TEVETEN PLUS.• Tell your doctor immediately if you become pregnant or
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	<p>are breast-feeding while taking TEVETEN PLUS.</p> <ul style="list-style-type: none"> • Drink enough water during exercise and hot weather when you are taking TEVETEN PLUS, especially if you sweat a lot.
Things you should not do	<ul style="list-style-type: none"> • 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.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how TEVETEN PLUS affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Keep the pack in a cool, dry place (below 25°C) in its original packaging.

- Do not store TEVETEN PLUS in the bathroom, near a sink or leave it in the car on hot days.
- Keep your tablets where young children cannot reach it.

For more information, see Section [5. What should I know while using TEVETEN PLUS?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor 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 or cough. **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 or itchiness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TEVETEN PLUS®

Active ingredient(s): *eprosartan mesilate and hydrochlorothiazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TEVETEN PLUS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TEVETEN PLUS.**

Where to find information in this leaflet:

- [1. Why am I using TEVETEN PLUS?](#)
- [2. What should I know before I use TEVETEN PLUS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TEVETEN PLUS?](#)
- [5. What should I know while using TEVETEN PLUS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TEVETEN PLUS?

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.

TEVETEN PLUS is used to lower 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.

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.

2. What should I know before I use TEVETEN PLUS?

Warnings

Do not use TEVETEN PLUS if:

- you are allergic to any medicine containing eprosartan, hydrochlorothiazide, sulfonamides or 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

Always check the ingredients to make sure you can use this medicine.

- 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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- 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
- are or have been taking diuretics (water/fluid) tablets.
- are on a salt restricted diet
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor can discuss with you the risks and benefits involved.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

4. How do I use TEVETEN PLUS?

How much to take

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.

- The usual dose of TEVETEN PLUS is one (1) tablet per day.
- Follow the instructions provided and use TEVETEN PLUS until your doctor tells you to stop.

When to take TEVETEN PLUS

- **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 to take TEVETEN PLUS

- **Swallow the tablet whole with a glass of water.**
- **Do not chew the tablet.**
- **You may take TEVETEN PLUS with or without food.**

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 use TEVETEN PLUS

TEVETEN PLUS should be used regularly at the same time each day.

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 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 use too much TEVETEN PLUS

If you think that you have used too much TEVETEN PLUS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while using TEVETEN PLUS?

Things you should 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.**
- **Remind any doctor, dentist or pharmacist you visit that you are using TEVETEN PLUS.**

Things you should 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.**

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in the original 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 destroy some medicines.

Keep TEVETEN PLUS where young children cannot reach it.

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

Getting rid of any unwanted medicine

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.

Do not use this medicine after the expiry date.

6. Are there any 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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 <p>These are common side effects of TEVETEN PLUS and usually short-lived.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● if you are on diabetic medication and you feel excessive thirst, nausea, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your</p>

Serious side effects	What to do
<p>vomiting or generally unwell</p> <ul style="list-style-type: none"> ● 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 <p>These side effects may require medical attention. These side effects are rare.</p> <ul style="list-style-type: none"> ● 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 	<p>nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain <p>These are serious side effects which may require urgent medical attention or hospitalisation. These side effects are very rare.</p> <ul style="list-style-type: none"> ● 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 <p>These are very serious side effects and may indicate a severe allergic reaction. These side effects are rare.</p>	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TEVETEN PLUS contains

Active ingredient (main ingredient)	Each tablet contains 600 mg eprosartan mesilate and 12.5 mg hydrochlorothiazide.
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose pregelatinized maize starch crospovidone

	magnesium stearate OPADRY II complete film coating system 85F27320 Butterscotch (ARTG PI No: 12291).
Potential allergens	TEVETEN PLUS contains lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What TEVETEN PLUS looks like

TEVETEN PLUS is a capsule shaped, butterscotch coloured, film-coated tablet, one side plain, the other side embossed 5147. (AUST R 143172).

Who distributes TEVETEN PLUS

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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TEVETEN® PLUS is a Viatris company trade mark

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