

TELMISARTAN/
HYDROCHLOROTHIAZIDE TEVA
80 mg/12.5 mg TABLETS

TELMISARTAN/
HYDROCHLOROTHIAZIDE TEVA
80 mg/25 mg TABLETS
Telmisartan/Hydrochlorothiazide

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

- What Telmisartan/Hydrochlorothiazide Teva Tablets is and what it is used for
- What you need to know before you take Telmisartan/Hydrochlorothiazide Teva Tablets
- How to take Telmisartan/Hydrochlorothiazide Teva Tablets
- Possible side effects
- How to store Telmisartan/Hydrochlorothiazide Teva Tablets
- Contents of the pack and other information

1 WHAT TELMISARTAN/
HYDROCHLOROTHIAZIDE TEVA
TABLETS IS AND WHAT IT IS USED
FOR

Telmisartan/Hydrochlorothiazide Teva Tablets is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Telmisartan/Hydrochlorothiazide Teva
80 mg/12.5 mg Teva Tablets

Telmisartan/Hydrochlorothiazide Teva Tablets is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when telmisartan is used alone.

Telmisartan/Hydrochlorothiazide Teva
80 mg/25 mg Teva Tablets

Telmisartan/Hydrochlorothiazide Teva Tablets is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not adequately controlled by Telmisartan/ Hydrochlorothiazide 80/12.5 mg or in patients who have been previously stabilised by telmisartan and hydrochlorothiazide given separately.

2 WHAT YOU NEED TO KNOW
BEFORE YOU TAKE TELMISARTAN/
HYDROCHLOROTHIAZIDE TEVA
TABLETS

Do not take Telmisartan/Hydrochlorothiazide Teva Tablets

- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are allergic to hydrochlorothiazide or to any other sulfonamide-derived medicines.
- if you are more than 3 months pregnant. (It is also better to avoid Telmisartan/ Hydrochlorothiazide Teva Tablets in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.
- if you have severe kidney disease.
- if your doctor determines that you have low potassium levels or high calcium levels in your blood that do not get better with treatment.
- if you have diabetes mellitus or impaired kidney function and you are treated with Rasilez.

If any of the above applies to you, tell your doctor or pharmacist before taking Telmisartan/ Hydrochlorothiazide Teva Tablets.

Warnings and precautions

Talk to your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea, vomiting, or haemodialysis.
- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Diabetes.
- Gout.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Systemic lupus erythematosus (also called “lupus” or “SLE”) a disease where the body’s immune system attacks the body.
- The active ingredient hydrochlorothiazide can cause an unusual reaction, resulting in a decrease in vision and eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to weeks of taking Telmisartan/Hydrochlorothiazide Teva Tablets. This can lead to permanent vision impairment, if not treated.

Talk to your doctor before taking Telmisartan/ Hydrochlorothiazide Teva Tablets:

- if you are taking Rasilez, a medicine used to treat high blood pressure.
- if you are taking digoxin.

You must tell your doctor if you think you are (or might become) pregnant. Telmisartan/ Hydrochlorothiazide Teva Tablets 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).

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Typical symptoms of fluid or electrolyte imbalance include dry mouth, weakness, lethargy, drowsiness, restlessness, muscle pain or cramps, nausea (feeling sick), vomiting, tired muscles, and an abnormally fast heart rate (faster than 100 beats per minute). If you experience any of these you should tell your doctor.

You should also tell your doctor, if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.

In case of surgery or anaesthetics, you should tell your doctor that you are taking Telmisartan/ Hydrochlorothiazide Teva Tablets.

Telmisartan/Hydrochlorothiazide may be less effective in lowering the blood pressure in black patients.

Children and adolescents

The use of Telmisartan/Hydrochlorothiazide in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Telmisartan/ Hydrochlorothiazide Teva Tablets :

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Telmisartan/ Hydrochlorothiazide Teva Tablets :

- Lithium containing medicines to treat some types of depression.
- Medicines associated with low blood potassium (hypokalaemia) such as other diuretics, (‘water tablets’), laxatives (e.g. castor oil), corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic), and salicylic acid and derivatives.
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors that may increase blood potassium levels.
- Heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. quinidine, disopyramide).
- Medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine).
- Other medicines used to treat high blood pressure, steroids, painkillers, medicines to treat cancer, gout, or arthritis, and vitamin D supplements.
- Rasilez, a medicine used to treat high blood pressure.
- Digoxin.

Telmisartan/Hydrochlorothiazide Teva Tablets may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine). Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking Telmisartan/Hydrochlorothiazide Teva Tablets.

The effect of Telmisartan/Hydrochlorothiazide Teva Tablets may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen).

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 Telmisartan/ Hydrochlorothiazide Teva Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan/ Hydrochlorothiazide Teva Tablets . Telmisartan/ Hydrochlorothiazide Teva Tablets is not recommended during 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. Telmisartan/ Hydrochlorothiazide Teva Tablets is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Driving and using machines

Some people feel dizzy or tired when taking Telmisartan/Hydrochlorothiazide. If you feel dizzy or tired, do not drive or operate machinery.

Telmisartan/Hydrochlorothiazide **contains milk sugar (lactose) and sorbitol.**

If you are intolerant to some sugars, consult your doctor before taking Telmisartan/ Hydrochlorothiazide.

3 HOW TO TAKE TELMISARTAN/
HYDROCHLOROTHIAZIDE TEVA
TABLETS

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

The recommended dose of Telmisartan/ Hydrochlorothiazide Teva Tablets is one tablet a day. Try to take a tablet at the same time each day. You can take Telmisartan/Hydrochlorothiazide Teva Tablets with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Telmisartan/Hydrochlorothiazide Teva Tablets every day until your doctor tells you otherwise.

If your liver is not working properly, the usual dose should not exceed 40 mg/12.5 mg once a day.

80 mg/12.5 mg: The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

80 mg/25 mg: The tablet can be divided into equal doses.

If you take more Telmisartan/Hydrochlorothiazide Teva Tablets than you should

If you accidentally take too many tablets contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Telmisartan/ Hydrochlorothiazide Teva Tablets

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you have 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.

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis* (often called “blood poisoning”), is a severe infection with whole-body inflammatory response, rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for Telmisartan/Hydrochlorothiazide.

Possible side effects of Telmisartan/ Hydrochlorothiazide Teva Tablets :

Common side effects (may affect up to 1 in 10 people):
Dizziness

Uncommon side effects (may affect up to 1 to 100 people):
Decreased blood potassium levels, anxiety, fainting (syncope), sensation of tingling, pins and needles (paraesthesia), feeling of spinning (vertigo), fast heart beat (tachycardia), heart rhythm disorders, low blood pressure, a sudden fall in blood pressure when you stand up, shortness of breath (dyspnoea), diarrhoea, dry mouth, flatulence, back pain, muscle spasm, muscle pain, erectile dysfunction (inability to get or keep an erection), chest pain, increased blood uric acid levels.

Rare side effects (may affect up to 1 in 1,000 people):
Inflammation of the lung (bronchitis), activation or worsening of systemic lupus erythematosus (a disease where the body’s immune system attacks the body, which causes joint pain, skin rashes and fever); sore throat, inflamed sinuses, feeling sad (depression), difficulty falling asleep (insomnia), impaired vision, difficulty breathing, abdominal pain, constipation, bloating (dyspepsia), feeling sick, inflammation of the stomach (gastritis), abnormal liver function (Japanese patients are more likely to experience these side effect), rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), redness of the skin (erythema), allergic reactions such as itching or rash, increased sweating, hives (urticaria), joint pain (arthralgia) and pain in extremities, muscle cramps, flu-like-illness, pain, increased levels of uric acid, low levels of sodium, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood

Adverse reactions reported with one of the individual components may be potential adverse reactions with Telmisartan/Hydrochlorothiazide, even if not observed in clinical trials with this product.

Telmisartan

In patients taking telmisartan alone the following additional side effects have been reported:

Uncommon side effects (may affect up to 1 to 100 people):
Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), urinary tract infections, deficiency in red blood cells (anaemia), high potassium levels, slow heart rate (bradycardia), kidney impairment including acute kidney failure, weakness, cough.

Rare side effects (may affect up to 1 in 1,000 people):
Sepsis* (often called “blood poisoning”, is a severe infection with whole-body inflammatory response which can lead to death), low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia), serious allergic reaction (e.g. hypersensitivity, anaphylactic reaction, drug rash), low blood sugar levels (in diabetic patients), upset stomach, eczema (a skin disorder), arthrosis, inflammation of the tendons, decreased haemoglobin (a blood protein), somnolence.

Very rare side effects (may affect up to 1 in 10,000 people):
Progressive scarring of lung tissue (interstitial lung disease)**

* The event may have happened by chance or could be related to a mechanism currently not known.

**Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.

Hydrochlorothiazide

In patients taking hydrochlorothiazide alone the following additional side effects have been reported:

Side effects of unknown frequency (frequency cannot be estimated from the available data):
Inflammation of the salivary gland, decreases in the number of cells in the blood, including low red and white blood cell count, low platelet count (thrombocytopenia), serious allergic reactions (e.g. hypersensitivity, anaphylactic reaction), decreased or loss of appetite, restlessness, light-headedness, blurred or yellowing of vision, decrease in vision and eye pain (possible signs of acute myopia or acute-angle closure glaucoma), inflammation of blood vessels (vasculitis necrotising), inflamed pancreas, upset stomach, yellowing of the skin or eyes (jaundice), lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body’s immune system attacks the body); skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, or blistering and peeling of the top layer of skin (toxic epidermal necrolysis), weakness, kidney inflammation or impaired kidney function, glucose in the urine (glycosuria), fever, impaired electrolyte balance, high blood cholesterol levels, decreased blood volume, increased levels of glucose, or fat in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail:imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE TELMISARTAN/ HYDROCHLOROTHIAZIDE TEVA TABLETS

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 after “EXP”. The expiry date refers to the last day of that month.

This medicinal product 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 Telmisartan/Hydrochlorothiazide Teva Tablets contains

80 mg/12.5 mg: The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.
80 mg/25 mg: The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients are
80 mg/12.5 mg: Sodium Hydroxide, Hypromellose, Sorbitol (E420), Meglumine, Mannitol (E421), Talc, Magnesium Stearate, Lactose Monohydrate, Hydroxypropylcellulose, Red Iron Oxide (E172)
80 mg/25 mg: Sodium Hydroxide, Hypromellose, Sorbitol (E420), Meglumine, Mannitol (E421), Talc, Magnesium Stearate, Lactose Monohydrate, Hydroxypropylcellulose, Yellow Iron Oxide (E172)

What Telmisartan/Hydrochlorothiazide Teva Tablets looks like and contents of the pack

80 mg/12.5 mg: Red and white to off white coloured capsule shaped bilayer tablet with a breakline on the red coloured side (dimension: approx. 16.5 x 8.0 mm).
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

80 mg/25 mg: Yellow and white to off white coloured capsule shaped bilayer tablet with a breakline on the yellow coloured side (dimension: approx. 18.0 x 8.0 mm).

The tablet can be divided into equal doses.

Telmisartan/Hydrochlorothiazide Teva Tablets is available in blister packs containing 7, 10, 14, 28, 28x1, 30, 30x1, 50x1, 56, 60, 84, 90, 90x1, 98, 100, 112, 120, 156 or 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Computerweg 10
3542 DR Utrecht
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Manufacturer

TEVA Pharmaceutical Works Private Limited Company
Pallagi út 13,
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TEVA SANTE
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France

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren
Germany

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)
Prilaz baruna Filipovica 25
10000 Zagreb
Croatia

This medicinal product is authorised in the Member States of the EEA under the following names:

France	Telmisartan - Hydrochlorothiazide Teva comprimé
Austria	Telmisartan/HCT ratiopharm Tabletten
Belgium	Telmisartan/HCTZ Teva tabletten
Bulgaria	Telmisartan/Hydrochlorothiazide Teva tablets
Cyprus	Telmisartan/HCTZ Teva δισκία
Czech Republic	Telmisartan/Hydrochlorothiazid ratiopharm
Germany	Telmisartan comp. ratiopharm Tabletten
Estonia	Telmisartan/Hydrochlorothiazide Teva
Greece	Telmisartan/HCTZ Teva δισκία
Spain	Telmisartan/Hidroclorotiazida ratiopharm comprimidos EFG
Finland	Telmisartan/Hydrochlorothiazide ratiopharm tabletti
Hungary	Telmisartan/HCT-ratiopharm tableta
Ireland	Telmisartan - Hydrochlorothiazide Teva Tablets
Italy	Telmisartan e Idroclorotiazide Teva
Lithuania	Telmisartan/ Hydrochlorothiazide Teva tabletės
Luxembourg	Telmisartan/HCTZ ratiopharm
Latvia	Telmisartan/ Hydrochlorothiazide Teva tabletes
Netherlands	Telmisartan/HCT Teva, tabletten
Norway	Telmisartan/Hydrochlorothiazide ratiopharm
Poland	Telmisartan HCT Teva
Portugal	Telmisartan + Hidroclorotiazida remfep
Romania	Telmisartan/Hidroclorotiazidă Teva comprimate
Slovenia	Telmisartan HCT Teva tablete
Slovakia	Telmisartan Hydrochlorotiazid Teva
United Kingdom	Telmisartan/Hydrochlorothiazide tablets

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