

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: TEVACARD CO 2,5/6,25; 5/6,25; 10/6,25
TEVACARD CO 2,5/6,25: 47/7.1.3/1269 TEVACARD CO 5/6,25: 47/7.1.3/1270 TEVACARD CO 10/6,25: 47/7.1.3/1271	Dosage form & strength: Film-coated tablets contain 2,5; 5 or 10 mg bisoprolol fumarate and 6,25 mg hydrochlorothiazide respectively
Date of registration: 16 March 2021	SAHPRA approval date: 12.05.2026

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S3

TEVACARD CO 2,5/6,25 (film-coated tablets)

TEVACARD CO 5/6,25 (film-coated tablets)

TEVACARD CO 10/6,25 (film-coated tablets)

Bisoprolol fumarate and hydrochlorothiazide

Sugar free

Read all of this leaflet carefully before you start taking TEVACARD CO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEVACARD CO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT TEVACARD CO IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEVACARD CO

3. HOW TO TAKE TEVACARD CO

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TEVACARD CO

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT TEVACARD CO IS AND WHAT IT IS USED FOR:

TEVACARD CO contains the active substances bisoprolol and hydrochlorothiazide:

- Bisoprolol belongs to a group of medicines called beta-blockers and is used to lower blood pressure.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics ('water tablets') and also helps to lower blood pressure by increasing urine output.

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TEVACARD CO is used to treat high blood pressure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEVACARD CO:

Do not take TEVACARD CO:

- if you are hypersensitive to bisoprolol, hydrochlorothiazide, other thiazides, sulphonamides or to any of the other ingredients of TEVACARD CO (listed in **section 6**)
- if your heart failure is not controlled by therapy, or cardiogenic shock (an acute serious heart condition causing low blood pressure and circulatory failure)
- if you have certain cardiac rhythm disorders, in particular slow heart rate causing problems, conduction disturbances or a disorder called sick sinus syndrome
- if you have severe asthma or certain severe forms of chronic bronchial diseases
- if you have severe blood circulation problems in your limbs (such as Raynaud's syndrome which may cause your fingers or toes to tingle or turn pale or blue)
- if you have untreated pheochromocytoma (tumour of the adrenal gland secreting substances which induce severe high blood pressure)
- if you have previously had or currently have cancer of the skin and/or lip
- if you have severe liver or kidney problems
- if you have increased blood acidity (metabolic acidosis) as a result of severe illness
- if you have low blood levels of potassium, not responding to treatment
- if you are pregnant or breastfeeding your baby
- if you are under the age of 18 years as safety and efficacy has not been established in children.

Warnings and precautions:

Take special care with TEVACARD CO:

Never suddenly stop taking treatment, in particular if you suffer from certain heart disorders (ischaemic heart disease, for example angina pectoris).

Talk to your doctor before taking TEVACARD CO if you have:

- liver problems

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- chronic bronchial disease (asthma or chronic obstructive airway disease)
- if you are breastfeeding or intend to do so
- any heart disease such as heart failure, disturbances in heart rhythm, or Prinzmetal's angina
- blood circulation problems in your limbs (in particular Raynaud's syndrome)
- pheochromocytoma (tumour of the adrenal gland)
- diabetes
- psoriasis
- if you plan to have desensitisation therapy, because TEVACARD CO may make it more likely that you experience an allergic reaction, or that such a reaction may be more severe
- if you are going to have an anaesthetic (e.g. for surgery) because TEVACARD CO may influence how your body reacts to this situation
- thyroid disorders
- strict fasting
- if you have ever suffered from gout, as TEVACARD CO may enhance the risk for gout attacks
- if you have kidney problems
- if you intend to expose yourself to the sun or to artificial UV light, as a few patients have experienced skin rash after exposure to sunlight. In this case, you should protect your skin while you are treated with TEVACARD CO.
- if 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 TEVACARD CO.
- if 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 TEVACARD CO, seek medical attention immediately.
- if 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 TEVACARD CO. 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.

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Hydrochlorothiazide works by influencing the salt and water balance in your body. Your doctor may want to check this from time to time. This is especially important if you have additional conditions which may become worse if the electrolyte balance is disturbed. Your doctor will also check your levels of blood fats, uric acid, or blood glucose from time to time.

TEVACARD CO is not recommended at the same time as lithium (used to treat some psychiatric disorders) or medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (such as verapamil, diltiazem or bepridil) (see **Taking other medicines**).

Athletes should be aware that TEVACARD CO contains an active ingredient which may give a positive reaction in drug tests.

Children and adolescents:

TEVACARD CO is not for use in children.

Other medicines and TEVACARD CO:

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Especially talk to your doctor if you are taking one of the following:

- certain psychiatric medicines (lithium, pimozide, haloperidol, sulpiride)
- antidysrhythmic medicines (such as diltiazem, verapamil, bepridil, propafenone, cibenzoline, flecainide, lidocaine, amiodarone, sotalol)
- any antihypertensive medicines e.g. clonidine, methyldopa, moxonidine, rilmenidine, nifedipine, amlodipine, so called ACE inhibitors (e.g. ramipril, perindopril, trandalopril, perindopril etc.), so called angiotensin II receptor antagonists (e.g. valsartan, losartan etc.)
- eye drops for glaucoma treatment (e.g. timolol)

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- medicines for the treatment of diabetes mellitus (insulin, sulphonylureas, glinides e.g. glibenclamide, gliquidone, gliclazide, glipizide, glimepiride or tolbutamide) since bisoprolol could increase the risk of severely low blood glucose levels when used with these medicines
- digitalis (digoxin) medicine for heart failure
- non-steroidal anti-inflammatory drugs - pain killers such as ibuprofen, acetylsalicylic acid, diclofenac, naproxen
- gout medicines (e.g. allopurinol)
- cholestyramine, colestipol
- mefloquine to treat or prevent malaria
- corticosteroids (e.g. cortisone, prednisone, prednisolone)
- if you need a surgery under general anesthesia, the doctor must know you take TEVACARD CO.

TEVACARD CO with food:

Take TEVACARD CO with or without food, but it must be taken in the morning.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking TEVACARD CO.

Your doctor will advise you to take another medicine instead of TEVACARD CO, as it is not recommended during pregnancy. This is because hydrochlorothiazide crosses the placenta and its use after the third month of pregnancy may cause potentially harmful foetal and neonatal effects.

You should not take TEVACARD CO if you are breastfeeding your baby.

Driving and using machines:

TEVACARD CO may affect your ability to drive or use machines. Your individual response may influence your ability to concentrate and react. If this happens, do not drive vehicles or use machines.

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It is not always possible to predict to what extent TEVACARD CO may interfere with your daily activities.

You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which TEVACARD CO affects you.

3. HOW TO TAKE TEVACARD CO:

Do not share medicines prescribed for you with any other person.

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

The usual starting dose is one 2,5 mg/6,25 mg tablet daily. If the blood pressure-lowering effect of this dose is inadequate, the dose will be increased to one 5 mg/6,25 mg tablet daily and, if the response is still inadequate, to the maximum recommended dose of one 10 mg/6,25 mg tablet daily.

Take TEVACARD CO in the morning, with or without food. Swallow the tablet with some liquid. Do not chew.

Never suddenly stop taking treatment (see **If you stop taking TEVACARD CO**).

Children:

There is no experience with TEVACARD CO in children, therefore its use is not recommended for children.

Your doctor will tell you how long your treatment with TEVACARD CO will last. If you have the impression that the effect of TEVACARD CO is too strong or too weak, tell your doctor or pharmacist.

If you take more TEVACARD CO than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of an overdose may include low blood pressure, slow heartbeat, sudden heart problems, dizziness, nausea, sleepiness, sudden breathing problems, low blood sugar.

If you forget to take TEVACARD CO:

Do not take a double dose to make up for forgotten individual doses.

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If you stop taking TEVACARD CO:

Never stop taking TEVACARD CO except on your doctor's advice. Otherwise your condition could become much worse. If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

4. POSSIBLE SIDE EFFECTS:

TEVACARD CO can have side effects.

Not all side effects reported for TEVACARD CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEVACARD CO, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using TEVACARD CO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVACARD CO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent:

- slow heartbeat, impaired heart rate, worsening of heart failure
- breathing problems in patients with asthma or chronic bronchial disease
- increase in certain liver enzymes, inflammation of the liver, yellow colouring of skin and eyes (jaundice)
- widespread full-thickness epidermal necrosis develops, producing erythema, and sloughing of the skin and mucosa, involving internal and external surfaces. The skin has an appearance similar to a scald. It usually affects the trunk, face and one or more mucous membranes (Lyell syndrome or toxic epidermic necrolysis).

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These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- feeling of coldness or numbness in hands and feet
- stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation
- tiredness.

Less frequent side effects:

- decrease in number of white blood cells (leucopenia), or blood platelets (thrombocytopenia), severe reduction in low white blood cell counts (agranulocytosis)
- loss of appetite
- increased blood levels for uric acid or sugar
- disturbed balance of fluids and electrolytes (especially low potassium, sodium, magnesium and abnormally low level of the chloride ion in the blood) as well as high calcium levels
- condition of too little acid in your blood (metabolic alkalosis)
- sleep disorders, depression
- nightmares, hallucinations
- reduced tear secretion, visual disturbance
- irritation and redness of the eye (conjunctivitis)
- hearing problems
- drop in blood pressure after standing or sitting up
- allergic runny nose
- abdominal complaints, inflammation of the pancreas
- allergy-type reactions, such as itching, sudden flushing of the face or skin rash, also after exposure to sunlight, hives, small purple-red marks on the skin caused by bleeding under the skin (purpura)
- hair loss

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- onset or worsening of pre-existing scaly skin rash (psoriasis); onset of thick scaly patches (cutaneous lupus erythematosus)
- muscular weakness, muscular cramps, feeling weak
- erection disorders
- lack of energy
- chest pain
- increased blood levels for fat, cholesterol
- increased urine levels for sugar
- increase of blood-levels for creatinine or urea
- increased amylase levels (enzymes involved in digestion).

Side effects with unknown frequency:

- skin and lip cancer (non-melanoma skin cancer)
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)
- decrease in vision 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TEVACARD CO.

5. HOW TO STORE TEVACARD CO:

Store all medicine out of reach of children.

Store at or below 25 °C.

Keep the tablets in the blisters until required for use.

Do not use the tablets after the expiry date shown on the container.

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Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TEVACARD CO contains:

The active ingredients are bisoprolol fumarate and hydrochlorothiazide.

The other ingredients are:

Tablet core: colloidal anhydrous silica, calcium hydrogen phosphate (anhydrous), magnesium stearate, maize starch, microcrystalline cellulose.

Tablet coating: hypromellose, macrogol 400, polysorbate 80 (E433), titanium dioxide, iron oxide yellow, red and black E172 (2,5/6,25 mg) and talc, iron oxide yellow, red and black E172 (5/6,25 mg).

What TEVACARD CO looks like and contents of the pack:

TEVACARD CO 2,5/6,25: Yellow, film-coated, round tablet, debossed with '2,5' on one side of the tablet and 'BH' on the other side of the tablet.

TEVACARD CO 5/6,25: Pink, film-coated, round tablet, debossed with '5' on one side of the tablet and 'BH' on the other side of the tablet.

TEVACARD CO 10/6,25: White, film-coated, round tablet, debossed with '10' on one side of the tablet and 'BH' on the other side of the tablet.

TEVACARD CO is packed into blisters made of Aluminium 20 µm and laminate: Polyamide 25 µm/Aluminium 45 µm/PVC 60 µm.

These blisters are further packed into a carton with a package leaflet, according to the approved pack size.

Blisters are packed in carton boxes containing: 14, 28, 30, 56, 60, 90 and 100 tablets. Not all pack sizes may be marketed.

Holder of certificate of registration:

Teva Pharmaceuticals (Pty) Ltd,
Maxwell Office Park,
Magwa Crescent West,

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This leaflet was last revised in:

12 May 2026

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