Patient Information Leaflet

SCHEDULING STATUS

S3

ZIABETA 2,5 mg/6,25 mg, film-coated tablet

ZIABETA 5 mg/6,25 mg, film-coated tablet

ZIABETA 10 mg/6,25 mg, film-coated tablet

Bisoprolol fumarate and hydrochlorothiazide

Read this entire leaflet carefully before you start taking ZIABETA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZIABETA 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 ZIABETA is and what it is used for
2. What you need to know before you take ZIABETA
3. How to take ZIABETA
4. Possible side effects
5. How to store ZIABETA
6. Contents of the pack and other information

1. What ZIABETA is and what it is used for

ZIABETA 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. It also helps to lower blood pressure by increasing urine output.

ZIABETA is indicated for the treatment of hypertension (high blood pressure).

2. What you need to know before you take ZIABETA

Do not take ZIABETA:

- If you are hypersensitive (allergic) to bisoprolol, hydrochlorothiazide, sulphonamides or any of the other ingredients.
- If you have heart failure
- If you have very low blood pressure from any cause.
- Second or third degree heart block (without a pacemaker)
- Slow heartbeat (with less than 50 beats/min)
- Hypotension
- Asthma
- Phaeochromocytoma, a tumour associated with a high blood pressure
- Metabolic acidosis
- 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)
- Severe kidney impairment
- Severe liver impairment

Warnings and precautions

Do not stop ZIABETA therapy abruptly, especially if you have coronary heart disease as this may lead to worsening of your heart condition.

Use ZIABETA with special care if:

- You have sugar diabetes as symptoms of hypoglycaemia (e.g. palpitations or sweating) may be masked.
- You are fasting
- You are receiving ongoing desensitisation therapy. ZIABETA may increase both the sensitivity to allergens and the severity of anaphylactic reactions.
- You have first degree AV block
- You have Prinzmetal's angina
- You are undergoing general or regional anaesthesia - inform your doctor
- You suffer from psoriasis
- You are a photosensitive individual

In addition, tell your doctor:

- If you have ever suffered from gout, as ZIABETA may enhance the risk for gout attacks;
- If you are going to have anaesthesia (e.g. for surgery) because ZIABETA may influence how your body reacts to this situation;
- If you plan to have desensitisation therapy, because ZIABETA may make it more likely that you experience an allergic reaction, or such a reaction may be more severe;
- If you are breastfeeding or intend to do so;
- If you intend to expose yourself to the sun or to artificial UV light, as some patients have experienced skin rash after exposure to sunlight. In this case, you should protect your skin while

you are treated with ZIABETA;

- 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 ZIABETA;
- If you experience acute onset of decreased visual acuity or ocular pain within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma (a disorder affecting the eye) can lead to permanent vision loss, so inform your doctor about this immediately.

If you have chronic lung disease or asthma, please inform your doctor immediately if you start to experience new difficulties in breathing, cough, or wheezing after exercise, when using ZIABETA.

Additional tests

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.

The concomitant use of this medicine is not recommended with 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 section “Taking other medicines”).

Children and adolescents

Experience with ZIABETA in paediatric patients is limited, therefore its use cannot be recommended in this population.

Taking other medicines and ZIABETA

Always tell your health care provider if you are taking any other medicine(s). (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ZIABETA with these medicines may cause undesirable interactions. Such medicines include:

- Medicines that correct the rhythm of your heart
- Medicines that stimulate or suppress your nervous system
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (known as Calcium antagonists of the verapamil type)
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa. However, do not stop taking these medicines without checking with your doctor first.
- Certain medicines used to treat irregular or abnormal heartbeat. Medicines such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide.
- Certain medicines used to treat high blood pressure or angina pectoris (known as Calcium antagonists of the dihydropyridine type (e.g. nifedipine)
- Parasympathomimetic medicines such as acetylcholine, methacholine, carbachol.
- Topical application of beta-blockers such as eye drops for treatment of glaucoma
- Insulin and oral mediation used to treat diabetes
- Anaesthetic agents, (for example during surgery)
- Digoxin used to treat heart failure
- Non-steroidal anti-inflammatory medicines, used to treat arthritis, pain or inflammation
- Beta-sympathomimetics (e.g. dobutamine, isoprenaline)
- Sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of

heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for the treatment of allergic reactions if ZIABETA is taken at the same time.

- Any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants), certain medicines used to treat epilepsy or during anaesthesia (barbiturates), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines)
- Mefloquine, used for prevention or treatment of malaria
- Depression treatment medicines called monoamine oxidase inhibitors
- Lithium, used to treat some psychiatric disorders
- Medicines which decrease blood levels of potassium (e.g. corticosteroids, furosemide)
- Medicines used to treat parkinsonism and pregnancy related hypertension (methyldopa)
- Corticosteroids

ZIABETA with food and drink

ZIABETA may be taken with or without food but must be taken in the morning.

Pregnancy and breastfeeding

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 health care provider for advice before taking ZIABETA.

ZIABETA is not recommended during pregnancy and breastfeeding.

Driving and using machines

ZIABETA may cause your blood pressure to drop and cause dizziness. This may affect your ability to drive or use machines.

3. How to take ZIABETA

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

Always use ZIABETA exactly as your doctor has instructed you. Your doctor will decide which dose is applicable to you. You should check with your doctor or pharmacist if you are unsure.
The recommended dosage is one tablet (ZIABETA 2,5/6,25 mg) once daily.
If necessary, the dosage may be increased to ZIABETA 10/6,25 mg once daily.
The film-coated tablets are to be swallowed whole with some liquid in the morning before, during or after breakfast.
ZIABETA is not indicated for use in children.

If you take more ZIABETA than you should

If you take more ZIABETA than your normal dose, contact your doctor or nearest hospital immediately.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison information centre.

If you forget to take ZIABETA

Do not take a double dose to make up for a forgotten dose, please consult your doctor.

If you stop taking ZIABETA

ZIABETA therapy should not be stopped abruptly.

If you have the impression that the effect of ZIABETA is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

4. Possible side effects

ZIABETA can cause side effects.

Not all side effects reported for ZIABETA are included in this leaflet. Should your general health worsen while taking ZIABETA, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects are:

- Dizziness, headache
- Gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation
- Feeling of coldness or numbness in the hands and feet
- Fatigue (tiredness)

Less frequent side effects are:

- Heart failure
- Irregular heartbeats
- Tightening of the chest in patients with bronchial asthma
- Slow pulse rate
- Muscle weakness or numbness, muscle cramps
- Depression, sleep disorders
- Hypotension, low blood pressure
- Stomach complaints
- Loss of appetite

- Hyperglycaemia, hyperuricaemia, disturbances of fluid and electrolyte balance
- Increase in the blood markers for liver and kidney function
- Increased blood fats
- Reduced tear flow, visual disturbances
- Hearing disorders
- Allergic rhinitis, runny, itchy nose and ears
- Hypersensitivity reactions (itching, flush, rash)
- Hepatitis, jaundice, a yellow colour will be seen on skin, mucous membrane and in the eyes
- Problems with erections
- Nightmares, hallucinations
- Decrease in the number of white blood cells (Leucopenia), or blood platelets (thrombocytopenia)
- Fainting
- Increase in liver enzymes
- Conjunctivitis (pink eye)
- Hair loss
- Worsening of or triggering of psoriasis
- Lowered white blood cells
- Change in the acidity of your blood
- Pancreatitis, inflammation of your pancreas with abdominal pain
- Chest pain

Frequency not known: Skin and lip cancer (Non-melanoma skin cancer)

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 the South African Health Products Regulatory Authority (SAHPRA) via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZIABETA.

5. How to store ZIABETA

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C. Store in the original package in order to protect from light.

Do not use after the expiry date stated on the vials and carton.

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 ZIABETA contains

The active ingredients are bisoprolol fumarate and hydrochlorothiazide.

The other ingredients are:

ZIABETA 2,5 mg/6,25 mg, film-coated tablet

Tablet core: Calcium hydrogen phosphate, magnesium stearate, maize starch, microcrystalline cellulose, crospovidone.

Film coating: Polysorbate, hypromellose, iron oxide, macrogol, titanium dioxide.

ZIABETA 5 mg/6,25 mg, film-coated tablet

Tablet core: Calcium hydrogen phosphate, magnesium stearate, maize starch, microcrystalline cellulose, silica, colloidal.

Film coating: Polysorbate, hypromellose, iron oxide, macrogol, titanium dioxide.

ZIABETA 10 mg/6,25 mg, film-coated tablet

Tablet core: Calcium hydrogen phosphate, magnesium stearate, maize starch, microcrystalline cellulose, silica, colloidal.

Film coating: Polysorbate, hypromellose, macrogol, titanium dioxide.

What ZIABETA looks like and contents of the pack

ZIABETA 2,5/6,25 mg: Yellow, round, biconvex film-coated tablet, upper side embossed with a heart, downside embossed with 2,5.

ZIABETA 5/6,25 mg: Pink, round, biconvex film-coated tablet, upper side embossed with a heart, downside embossed with 5.

ZIABETA 10/6,25 mg: White, round, biconvex film-coated tablet, upper side embossed with a heart, downside with 10.

ZIABETA is available as 30 tablets in blisters of 10 tablets each.

Holder of Certificate of Registration

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