**Approved Patient Information Leaflet for Medicines for Human Use:**

**ZIDAFLO**

**SCHEDULING STATUS:** S3

**ZIDAFLO 12,5 mg Tablets**

**ZIDAFLO 25 mg Tablets**

**ZIDAFLO 50 mg Tablets**

**Hydrochlorothiazide**

**Contains Sugar**

**ZIDAFLO 12,5:**

**Each tablet contains 10 mg lactose monohydrate.**

**ZIDAFLO 25:**

**Each tablet contains 20 mg lactose monohydrate.**

**ZIDAFLO 50:**

**Each tablet contains 40 mg lactose monohydrate.**

**Read all of this leaflet carefully before you start taking ZIDAFLO**

- 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.
- ZIDAFLO 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 ZIDAFLO is and what it is used for

2. What you need to know before you take ZIDAFLO

3. How to take ZIDAFLO

4. Possible side effects

5. How to store ZIDAFLO

6. Contents of the pack and other information

## 1. What ZIDAFLO is and what it is used for

ZIDAFLO tablets contain the active substance hydrochlorothiazide. ZIDAFLO is a diuretic (medicine that increases urine output).

Thiazide diuretics are usually used to treat high blood pressure. They are also used ~~for~~ to treat congestive heart failure, accumulation of fluid and oedema.

## 2. What you need to know before you take ZIDAFLO

**Do not take ZIDAFLO**

- if you are hypersensitive (allergic) to hydrochlorothiazide, other medicines containing sulphonamides or any of the other ingredients of ZIDAFLO (listed in section 6).
- if you have severe kidney problems.
- if you have severe liver problems.
- if suffer from Addison's disease (when your adrenal glands, located just above your kidneys, produce too little cortisol and, often, too a little aldosterone).
- if you have too much calcium in your blood (hypercalcaemia).
- if you are in the second or third trimester of pregnancy.
- if you are breastfeeding your baby.

- if you have previously had or currently have cancer of the skin and/or lip.

**Warnings and precautions**

Take special care with ZIDAFLO:

- if you have liver problems.
- if you have high blood sugar. ZIDAFLO may cause increased blood sugar and aggravate or unmask diabetes mellitus (a disease that results in too much sugar in the blood with symptoms such as severe thirst, frequent urination, tiredness, weight loss and blurred vision). Your blood sugar concentrations should be monitored if you are taking any medicine to treat diabetes.
- if you suffer from high cholesterol and high triglyceride (a type of fat in your blood) levels, ZIDAFLO may increase these levels.
- if you have kidney problems.
- if you suffer from gout characterized by severe pain, redness and tenderness in joints, ZIDAFLO may cause an attack of this condition.
- if you are experiencing a dry mouth, thirst, weakness, tiredness, drowsiness, restlessness, confusion, fits, muscle pains, cramps or weakness, low blood pressure, passing a reduced amount of urine, a fast, irregular heartbeat, breathing problems or nausea and vomiting as these may be signs of disturbances of the amount of different salts in your body (electrolyte imbalances). You should be carefully observed for signs of fluid and electrolyte imbalance, especially if you are vomiting or receiving parenteral fluid (intravenous) therapy. If you are an elderly patient you may be more prone to electrolyte imbalances.
- if you have high calcium levels in your blood as ZIDAFLO may decrease excretion of calcium through the urine, which may cause increase calcium in the body.

- if you are going to have a test to measure the functioning of a gland situated in your neck behind your thyroid gland, called the parathyroid gland, ZIDAFLO should be discontinued before the test.
- if you have low magnesium levels in your blood as ZIDAFLO may increase the excretion of magnesium through the urine.
- if you are taking or have taken a medicine called corticotropin which may affect your heart and your heart medication.
- if you experience symptoms such as extreme fatigue, muscle weakness, breathing problems and feeling very thirsty, you may have chloride deficiency.
- if you suffer from a condition where you retain water (especially in hot weather), ZIDAFLO may cause a decrease in blood sodium.
- if you suffer from a chronic inflammatory disease of connective tissue, affecting the skin and various internal organs known as systemic lupus erythematosus. ZIDAFLO may exacerbate or activate this condition.
- if you are taking a medicine called lithium to treat a mental disorder.
- if you experience decreased vision and eye pain while taking ZIDAFLO you should stop taking ZIDAFLO and contact your doctor immediately as these symptoms may be caused by increased pressure in the eye (glaucoma). Your risk for developing this eye disorder is increased if you have a history of sulphonamide medicine or penicillin antibiotic allergy.
- 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 ZIDAFLO. 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.
- if you had a surgery to stop excessive sweating called a sympathectomy.
- if you are going to have an anti-doping test, ZIDAFLO could show a false positive result.

- if you have a history of allergy or asthma. ZIDAFLO may cause allergic reactions.
- if you are taking medicines for high blood pressure.
- if you have had skin cancer of if you develop an unexpected skin lesion during treatment with ZIDAFLO. Treatment with ZIDAFLO, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect you skin from sun exposure and UV rays while taking ZIDAFLO.

**Other medicines and ZIDAFLO**

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

The following medicines may interact with ZIDAFLO when used at the same time:

- muscle relaxants (such as baclofen, tubocurarine)
- other antihypertensives
- cholestyramine and colestipol resins (used to lower cholesterol levels)
- pressor amines (such as adrenaline)
- amphotericin B (antibiotic by injection), carbenoxolone (used to treat mouth sores), corticosteroids, hormones (such as corticotropin, adrenaline), stimulant laxatives (help with bowel movements)
- lithium (antidepressant)
- calcium salts
- digitalis (digoxin)
- antidysrhythmic medicines (such as sotalol, amiodarone) or capable of inducing Torsades de Pointes (a type of dysrhythmia) such as intravenous erythromycin, mizolastine
- antipsychotic medicines (such as haloperidol)
- carbamazepine (for epilepsy)
- tetracyclines (antibiotic)

- anticholinergic agents (such as atropine)
- medicines used to treat gout (such as probenecid, allopurinol)
- diazoxides (medicines used to treat hypoglycaemia)
- vitamin D
- ciclosporin (medicine used in transplant patients)
- medicines used to lower potassium levels
- amantadine (antiviral medicine)
- cytotoxic medicines (such as methotrexate, cyclophosphamide)
- medicines used to treat diabetes and oral insulin
- anti-inflammatory medicines (derivatives of salicylic acid, indomethacin)
- alcohol, medicines to make you sleep (such as barbiturates or narcotics)
- beta$_2$-agonists (such as salbutamol)

Hydrochlorothiazide can cause analytical interference in the diagnosis of some tests such as: bentiromide test (gastric test)

Thiazides may cause a decrease in the concentrations of GDP (protein-bound iodine) without any signs of thyroid disorder.

Because of their effects on calcium metabolism, thiazides may interfere with tests for parathyroid function.

The hydrochlorothiazide contained in this medicine could give a positive test result of anti-doping test.

**ZIDAFLO with food, drink and alcohol**

In combination with the intake of alcohol, this medicine may cause dizziness and may enhance orthostatic hypotension (low blood pressure that happens when standing up from sitting or lying down).

**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 this medicine.

ZIDAFLO is not recommended during pregnancy. Hydrochlorothiazide is eliminated in human milk, therefore its use in nursing mothers is not recommended.

**Driving and using machines**

ZIDAFLO has moderate influence on the ability to drive and use machines.

Since adverse reactions such as tiredness, dizziness and blurred vision have been reported in patients receiving ZIDAFLO, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ZIDAFLO does not adversely affect your ability to do so (see section 4).

It is not always possible to predict to what extent ZIDAFLO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZIDAFLO affects them.

**ZIDAFLO contains lactose**

ZIDAFLO tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take ZIDAFLO**

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

Always take ZIDAFLO exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

**Dose**

*For adults - For the treatment of oedema:*

An initial dose of 25 to 100 mg is usually given, and later reduced to a smaller maintenance dose, often given on alternative days.

*For adults – in the treatment of mild to moderate hypertension:*

12,5 mg daily.

*For adults - As an adjunct in the treatment of hypertension:*

25 – 100 mg daily in conjunction with a reduced dose of the hypotensive agent.

**Method of administration**

The tablet should be taken orally.

If a single dose is indicated, it should preferably be taken in the morning to minimise the effect of increased frequency of urination.

**If you take more ZIDAFLO than you should**

If you have taken more ZIDAFLO than you should, severe hypotension (drastic reduction in blood pressure), unconsciousness, nausea, drowsiness, thirst, muscle aches, difficulty in walking, cardiac dysrhythmias, reduced heart rate and kidney failure.

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

**If you forget to take ZIDAFLO**

The missed dose should be taken as soon as you remember. Skip the missed dose if it’s time for the next dose. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking ZIDAFLO**

Do not stop taking ZIDAFLO without consulting your doctor or pharmacist. If you have the impression that the effect of ZIDAFLO is too strong or too weak, tell your doctor or pharmacist.

## 4. Possible side effects

ZIDAFLO can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off known as toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZIDAFLO. 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:

- abnormal, irregular heart rhythm, muscle weakness and twitching that could be caused by low blood levels of potassium
- seizures (fits)
- a sore or ulcer that develops on the lining of the food pipe (oesophagus), stomach or small intestine with symptoms such as upper abdominal pain
- yellow pigmentation of skin and eyes caused by liver or blood problems (jaundice)
- inflammation of the pancreas which causes severe pain in the abdomen and back
- serious decrease of blood cells which can cause weakness, bruising or make infections more likely excessive fluid accumulation in lungs
- kidney failure, swelling and inflammation in between the kidney tubules
- too few white blood cells known as neutropenia
- inflammation of the lungs which causes breathlessness, cough and raised temperature (pneumonitis), difficulty breathing
- skin cancer (skin cancer may be a sore that does not heal or comes back after healing, pale, white or yellow flat areas that look like scars, raised and scaly red patches, small, smooth and shiny lumps that are pearly white, pink or red, pink growths with raised edges and indents in the centre or growths that has small blood vessels on the surface).

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- electrolyte imbalances, decrease in chloride in the blood, low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (may occur in patients with severe heart failure who have swelling due to retained fluid, especially with large doses of ZIDAFLO in conjunction with restricted salt in the diet)
- stomach and intestine complaints, dry mouth

- thirst, weakness
- mental and physical sluggishness, drowsiness
- restlessness
- muscle pain and cramps
- reduced urine production.

Less frequent side effects:

- metabolic (physical and chemical processes necessary to maintain life) disturbances especially at high doses
- high blood sugar and the presence of glucose in the urine (glycosuria) in diabetic and other susceptible patients
- increased levels of uric acid in the blood that causes attacks of gout in some patients
- the urinary excretion of calcium is reduce
- deficiency of magnesium in the blood
- harmful changes in plasma lipids (fats)
- loss of appetite, stomach irritation, nausea, vomiting, constipation, diarrhoea
- headache, dizziness
- increased sensitivity of skin to sun
- numbness, tingling, pins and needles, cold, warmth, tingling pressure of the skin (paraesthesia)
- a fall in blood pressure on standing up which causes dizziness or fainting (postural hypotension)
- yellow vision
- inflammation of a salivary gland
- sense of spinning (vertigo)
- loss of male sexual ability.

Side effects with frequency unknown:

- Skin and lip cancer (non-melanoma skin cancer)
- Decreased vision or pain in the eyes
- fever
- light-headedness
- feelings of sadness or worthlessness (depression), sleep disturbances
- muscle spasm
- kidney problems
- temporary blurred vision
- hair loss
- increases in blood levels of fat in your blood called cholesterol and triglycerides,
- an inflammation of blood vessel walls (inflammation of blood vessels, often with skin rash, inflamed blood vessels in the skin),
- small purple coloured spots caused by bleeding into the skin,
- 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 or 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 ZIDAFLO**.**

**5. How to store ZIDAFLO**

Store all medicines out of reach of children

Store at or below 25 ºC.

Store in original packaging to protect it from light.

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 ZIDAFLO contains

- The active substance is hydrochlorothiazide
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, Methylhydroxyethylcellulose, microcrystalline cellulose and purified water.

### What ZIDAFLO looks like and contents of the pack

ZIDAFLO 12,5 are white to off white, round shaped, flat face, beveled edge tablets debossed with “L” on one side and “7” on other side.

ZIDAFLO 25 are white to off white, round shaped, biconvex tablets debossed with “J” on one side and “2” on other side.

ZIDAFLO 50 are white to off white, round shaped, biconvex tablets debossed with “J 7” on one side and break line on other side.

ZIDAFLO is supplied in clear PVC / aluminium blister packs. The blisters are subsequently packed into cardboard boxes.

Pack sizes: 28’s, 30’s, 56’s, 84’s, 100’s and 112’s tablets.

Not all pack sizes may be marketed.

### Holder of Certificate of Registration

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**Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet**

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL:

https://austell.co.za/product-info/

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