Proposed Clean Patient Information Leaflet for Medicines for Human Use:
Hydrochlorothiazide 25 Gulf tablets

SCHEDULING STATUS: S3

Hydrochlorothiazide 25 Gulf, tablets

Hydrochlorothiazide

Contains sugar: Lactose anhydrous 72 mg/tablet

Read all of this leaflet carefully before you start taking Hydrochlorothiazide 25 Gulf

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.
- Hydrochlorothiazide 25 Gulf 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 Hydrochlorothiazide 25 Gulf is and what it is used for
2. What you need to know before you take Hydrochlorothiazide 25 Gulf
3. How to take Hydrochlorothiazide 25 Gulf
4. Possible side effects
5. How to store Hydrochlorothiazide 25 Gulf
6. Contents of the pack and other information

1. What Hydrochlorothiazide 25 Gulf is and what it is used for

Hydrochlorothiazide 25 Gulf belongs to a group of medicines known as thiazide diuretics.

Diuretics help the body to get rid of extra fluid by increasing the excretion of electrolytes and

fluid from the body and are used in patients with high blood pressure. Because they get rid of fluid, diuretics are sometimes called ‘water tablets’.

Hydrochlorothiazide 25 Gulf is used in the treatment and management of:

- Swelling due to retained fluid (oedema) due to salt and water retention, or due to serious heart, liver or kidney problems
- Diabetes insipidus (a condition which causes abnormally large amounts of urine to be passed and increased thirst) where Hydrochlorothiazide 25 Gulf may be of value in managing this disease due to it having the opposite effect of retaining fluids in the body (antidiuretic effect) in these patients
- High blood pressure that has an unknown cause (essential hypertension), in combination with or without other specific medicines used to treat high blood pressure.

2. What you need to know before you take Hydrochlorothiazide 25 Gulf

Do not take Hydrochlorothiazide 25 Gulf:

- if you are hypersensitive (allergic) to hydrochlorothiazide, other medicines containing sulfonamides or any of the other ingredients of Hydrochlorothiazide 25 Gulf (listed in section 6)
- if you have severe kidney problems
- if you have severe liver problems
- if you have Addison's disease when your adrenal glands, located just above your kidneys, does not produce enough steroid hormones – e.g. too little cortisol and, often, too little aldosterone)
- if you have too much calcium in your blood (hypercalcaemia)
- if you have previously had or currently have cancer of the skin and/or lip
- if you are in the second or third trimester of pregnancy
- if you are breastfeeding your baby

- if you are taking lithium, a medicine used to treat depression (see sections “Warnings and precautions” and “Other medicines and Hydrochlorothiazide 25 Gulf”)

Warnings and precautions

Take special care with Hydrochlorothiazide 25 Gulf:

- if you have severe liver problems the small changes caused by Hydrochlorothiazide 25 Gulf in the amount of different salts in your body (electrolytes) in your blood, may cause the loss of brain function which can include forgetfulness, confusion and breath with a sweet or musty odour and can progress to shaking of the hands or arms, disorientation and slurred speech and loss of consciousness (coma). If you experience these symptoms, stop taking Hydrochlorothiazide 25 Gulf and contact your doctor immediately
- if you have kidney problems, you may show elevated levels of urea and other nitrogen compounds in the blood (azotaemia) and produce abnormally small amounts of urine than what is usual for you (oliguria) and your kidneys’ ability to remove waste and balance fluids in your body become progressively worse. Your doctor might discontinue the use of Hydrochlorothiazide 25 Gulf
- if you suffer from very high levels of uric acid in your blood, Hydrochlorothiazide 25 Gulf may trigger a gout attack which is characterised by severe pain, redness and tenderness in your joints
- if you have high blood sugar, Hydrochlorothiazide 25 Gulf 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 are experiencing symptoms of a disturbances of the amount of different salts in your body (electrolyte imbalances) such as 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. If you are an elderly patient you may be more prone to 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 experience a sudden drop in blood pressure when standing up after sitting or lying down (orthostatic hypotension) which can make you feel lightheaded or dizzy when you stand, causing blurred eyesight, weakness and fainting
- if you experience symptoms of having too much calcium in your blood (hypercalcaemia) such as excessive thirst, frequent urination. upset stomach, nausea, vomiting, constipation. bone pain. muscle weakness, confusion, feeling very tired and having very fast heartbeats (palpitations) and other changes in the way your heart beats. You should contact your doctor if you develop these signs and symptoms that might indicate hypercalcemia
- if you develop a blood level that is below normal in potassium, an important body chemical (hypokalaemia). The problem can result in fatigue, muscle cramps and abnormal heart rhythms. You should contact your doctor
- if you develop symptoms of metabolic alkalosis, a condition where the pH of tissue is elevated beyond the normal range, such as confusion (this can progress to a state of state of near-unconsciousness or insensibility or complete unconsciousness), shaking of your hands, light-headedness, muscle twitching, nausea, vomiting, numbness or tingling in the face, hands, or feet and prolonged muscle spasms (tetany). You should contact your doctor
- if you develop symptoms of low sodium concentration in your blood (hyponatraemia) such as confusion, irritability, disorientation in mild cases to seizures (fits), brain swelling and coma in serious cases which can be life-threatening, you should contact your doctor
- if you experience symptoms related to low magnesium levels in your blood (hypomagnesaemia) such as shaking, muscle spasms, muscle cramps and/or numbness

in your hands and feet, abnormal eye movements (nystagmus), fatigue and weakness, fits, confused thinking and a lack of awareness of your surroundings (delirium) and abnormal heart rhythms (dysrhythmia). You should contact your doctor if you experience any of these symptoms

- 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 Hydrochlorothiazide 25 Gulf. 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 skin cancer or if you develop an unexpected skin lesion during treatment with Hydrochlorothiazide 25 Gulf. Treatment with Hydrochlorothiazide 25 Gulf, 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 Hydrochlorothiazide 25 Gulf
- if you suffer from systemic lupus erythematosus (SLE), a chronic condition in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels and can be life-threatening in severe cases (see also section 2). Hydrochlorothiazide 25 Gulf may activate or worsen this condition
- if you are taking blood pressure medicines (antihypertensives) used to bring your blood pressure down, as Hydrochlorothiazide 25 Gulf can make your blood pressure drop too low and cause you to experience confusion, dizziness, nausea, fainting (syncope), fatigue, neck or back pain, headache, blurred vision, heart palpitations, or feelings that your heart is skipping a beat, fluttering, or beating too hard or too fast
- if you suffer from high cholesterol and high triglyceride (types of fat in your blood) levels as Hydrochlorothiazide 25 Gulf may increase these levels
- if you have a history of allergy or asthma as Hydrochlorothiazide 25 Gulf may cause

allergic reactions

- if you develop an inflammation of the organ lying behind the lower part of the stomach (pancreas) causing severe upper belly pain that may spread to your back or chest (it may feel worse after you eat), nausea and vomiting
- if you are taking lithium to treat a mental disorder, since the combination with Hydrochlorothiazide 25 Gulf may lead to toxic blood concentrations of lithium which can include feeling weak, having a worsening tremor, feeling unbalanced or uncoordinated, poor concentration, diarrhoea, severe nausea, vomiting, slurred speech and confusion
- if you had a surgery to stop excessive sweating called a sympathectomy as Hydrochlorothiazide 25 Gulf can then make your blood pressure drop too low
- if you are going to have an anti-doping test, Hydrochlorothiazide 25 Gulf could show a false positive result.

Other medicines and Hydrochlorothiazide 25 Gulf

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

- Hydrochlorothiazide 25 Gulf can interact with the following medicines to make their effect and risk of adverse effects stronger. If you are taking any of the following, your doctor might monitor you more closely:
    - Calcium salts used to treat calcium deficiency as there can be an increase in your calcium blood levels (see section “Warnings and precautions” above)
    - Medicines to treat problems with the way the heart beats such as digoxin as this can cause too low potassium levels in your blood, your doctor might change your treatment
    - Skeletal muscle relaxants (e.g., tubocurarine) used to produce muscle relaxation and often used during surgery
    - Antihypertensive medicines (e.g. enalapril, perindopril), used to treat high blood pressure (see section “Warnings and precautions” above)

- Lithium used to treat mental disorders (see section “Warnings and precautions” above)
- Anti-dysrhythmic medicines (amiodarone, sotalol, adenosine, verapamil, flecainide acetate) used to treat heart rhythm disorders. This can cause a specific type of abnormal heart rhythm that can lead to sudden cardiac death (Torsades de Pointes)
- Antipsychotics (e.g., flupentixol, fluphenazine, haloperidol) which are medicines used to treat mental disorders such as an inability to think, feel and behave clearly (schizophrenia) and a disconnection from reality (psychosis).
- Metformin (used to help lower blood sugar levels in people with type 2 diabetes) – you may have an increased risk of lactic acid building up in your blood (lactic acidosis) causing symptoms like confusion and fatigue and possible kidney problems
- Medicines used to treat gout (such as probenecid, allopurinol). You may experience hypersensitivity reactions such as itching and rash
- Amantadine (medicine for Parkinson’s disease also used to treat or prevent certain illnesses caused by viruses)
- Medicines that stops the growth of cells, including cancer cells (cytostatics) used in the treatment of cancer (cyclophosphamide) or to treat rheumatoid arthritis, juvenile idiopathic arthritis, vasculitis and psoriatic arthritis (methotrexate)
- Quinidine (used to manage and treat certain types of irregular heartbeats and malaria in patients).

- Hydrochlorothiazide 25 Gulf can interact with the following medicines to make their effect weaker:
  - Antidiabetic medicines (insulin and oral antidiabetics) used to treat high sugar in the blood caused by diabetes mellitus. Hydrochlorothiazide 25 Gulf can increase blood sugar levels and interfere with diabetic control. You may need a dose adjustment or more frequent monitoring of your blood sugar to safely use both medicines
  - Noradrenaline (norepinephrine) and adrenalin (epinephrine) used to treat low blood

pressure in specific situations and serious allergic reactions.

- Some medicines can interact with Hydrochlorothiazide 25 Gulf to make its effect and risk of adverse effects stronger. If you are taking the medicines below, your doctor might monitor you more closely.
  - The following medicines can interact with Hydrochlorothiazide 25 Gulf and decrease levels of potassium in your blood below acceptable levels (hypokalaemia) which can cause attacks of severe muscle weakness, eventually leading to paralysis and possibly respiratory failure (when your lungs cannot get enough oxygen into your blood or remove enough carbon dioxide) (see “Warnings and precautions” above):
    - Some water tablets (e.g., furosemide)
    - ACTH or corticotropin used to test if you have problems with your adrenal gland e.g., when you have Addison’s disease or to treat multiple sclerosis in adults and spasms in children.
    - Amphotericin B (injection) used to treat fungal infections
    - Beta2-agonists (e.g., salbutamol, albuterol) used to treat asthma
    - Carbenoxolone used to treat stomach ulcers
    - Corticosteroids (e.g., prednisone, methylprednisone) used as anti-inflammatory medicine and to prevent an immune response
    - Stimulant laxatives (e.g., bisacodyl, senna) used to treat constipation
    - Penicillin G sodium, an injectable antibiotic
    - Salicylic acid and derivatives (e.g. aspirin) used to treat pain, fever and inflammation.
  - The following medicines can interact with Hydrochlorothiazide 25 Gulf and increase the side effect of postural hypotension which is low blood pressure that happens when standing after sitting or lying down causing dizziness and possibly fainting (see “Warnings and precautions” above):

- Alcohol
- Barbiturates (e.g., phenobarbital) which are used to calm you or induce sleep (sedatives)
- Opioids (e.g., morphine, oxycodone, tramadol, codeine) used to treat pain
- Phenothiazines (e.g. chlorpromazine and promethazine) used to treat serious mental and emotional disorders, including schizophrenia and other psychotic disorders
- Tricyclic antidepressants (e.g. amitriptyline, clomipramine, nortriptyline, imipramine) used to treat depression as well as manage a variety of other conditions.

- Baclofen (a skeletal muscle relaxant used for treatment of multiple sclerosis or certain injuries to the spine) can strengthen the blood pressure lowering effect of Hydrochlorothiazide 25 Gulf. Your doctor may monitor your blood pressure and renal function and may adapt your dosage of the Hydrochlorothiazide 25 Gulf
- The following medicines can interact with Hydrochlorothiazide 25 Gulf and decrease levels of sodium in your blood below acceptable levels (hyponatraemia) which can cause you to experience nausea and vomiting, confusion, seizures, or lost consciousness (see “Warnings and precautions” above):
    - Carbamazepine used to treat recurrent fits (epilepsy)
    - Selective serotonin reuptake inhibitors (SSRIs) (for example citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, vortioxetine) used to treat depression.
- Anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia) such as atropine and biperiden
- The following medicines can interact with Hydrochlorothiazide 25 Gulf and increase

levels of uric acid in your blood which can lead to health problems such as gout and kidney stones (see “Warnings and precautions” above):

- Tetracyclines (antibiotic) used to treat a number of infections
- Ciclosporin (medicine which is used in the case of organ transplants)

- Vitamin D – you may experience increased levels of calcium in your blood (see “Warnings and precautions” above)
- Diazoxides (medicines used to treat hypoglycaemia) and beta blockers (used to manage abnormal heart rhythms, to treat heart cramps/chest pain and reduce high blood pressure). You may experience excessive increase in blood sugar levels
- Methyldopa (used in the management and treatment of high blood pressure) – you may develop a disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia).

- Some medicines can interact with Hydrochlorothiazide 25 Gulf to make its effect weaker:
  - Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., indometacin, ibuprofen), including COX-2 inhibitors (e.g., celecoxib, etoricoxib) used to treat pain, fever, inflammation and blood clots (e.g., aspirin)
  - Colestyramine resin and colestipol used to treat high cholesterol (a type of fat in your body that helps your body perform many important jobs).

- Hydrochlorothiazide 25 Gulf can change the results of some laboratory tests:
  - Laboratory tests for parathyroid function: Blood or urinary tests to test the function of the parathyroid glands (four small glands that lie behind the thyroid in the neck and produce parathyroid hormone, which plays a role in regulating the body's blood level of calcium and phosphorus)
  - Laboratory tests for pancreas function: Blood or urinary tests to test the function of the pancreas (an organ located in the abdomen that plays an essential role in converting

the food we eat into fuel for the body's cells by helping in digestion and regulating blood sugar)

- Laboratory tests for thyroid function.

Hydrochlorothiazide 25 Gulf with food, drink and alcohol

The tablets should be swallowed with a glass of water and should be taken with or after meals to minimise stomach upset.

Do not take Hydrochlorothiazide 25 Gulf with alcohol as you can have an increased risk of dizziness and possibly fainting.

Pregnancy and breastfeeding

You should not take Hydrochlorothiazide 25 Gulf while you are pregnant or breastfeeding your baby.

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.

Driving and using machines

It is not always possible to predict to what extent Hydrochlorothiazide 25 Gulf may interfere with your daily activities. Hydrochlorothiazide 25 Gulf has a moderate influence on the ability to drive and use machines. Hydrochlorothiazide 25 Gulf can cause possible side effects such as drowsiness. fits (seizures), dizziness, problems with your vision and a sensation of feeling off balance (vertigo).

When Hydrochlorothiazide 25 Gulf is taken with alcohol, barbiturates, opioids or other antihypertensives, it increases the risk of postural hypotension.

You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which Hydrochlorothiazide 25 Gulf affects you (see section 4).

Hydrochlorothiazide 25 Gulf contains lactose anhydrous

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Hydrochlorothiazide 25 Gulf.

3. How to take Hydrochlorothiazide 25 Gulf

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

Always take Hydrochlorothiazide 25 Gulf exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment should be started at the lowest dose needed to achieve the desired effect.

Treatment should be suited to the individual patient.

The usual dose is:

Adults

In the treatment of swelling due to retained fluid (oedema)

An initial daily dose of one tablet (25 mg) to four tablets (100 mg) is usually given, and later reduced to a smaller maintenance dose suitable to you when water retention in the body is controlled, often this can mean that you will be taking a lower dose on alternative days.

An initial dose of up to eight tablets (200 mg) may be necessary in some patients, but larger doses have no additional effect.

In the treatment of high blood pressure (hypertension)

One tablet (25 mg) to four tablets (100 mg) daily in conjunction with a reduced dose of the hypotensive medicine.

Children

The correct dosage for your child will be determined by your doctor and is usually 2,5 mg per kg body mass daily in two divided doses (e.g., in the morning and in the evening).

Your doctor will ensure that the dosage you or your child take is not higher than necessary to achieve the desired effect. Do not increase or decrease your/your child's dose without prior consultation with your doctor.

If you or your child take Hydrochlorothiazide 25 Gulf for a long time, it may cause lower levels of potassium in your blood (hypokalaemia) (see section 2). You/your child may need to take potassium supplements.

Your doctor will tell you how long your treatment with Hydrochlorothiazide 25 Gulf will last. Do not stop treatment early because it may affect your condition.

If you have the impression that the effect of Hydrochlorothiazide 25 Gulf is too strong or too weak, tell your doctor or pharmacist.

Method of administration

Hydrochlorothiazide 25 Gulf tablets must be taken by mouth after food with a drink of water to minimise the possibility of disturbances of the digestive tract such as nausea.

If you take more Hydrochlorothiazide 25 Gulf than you should

When more Hydrochlorothiazide 25 Gulf was taken than you should take, it can lead to a loss of body fluid (dehydration) and disturbances of the amount of different salts in your body (electrolyte imbalances) such as a dry mouth, thirst, weakness, dizziness, 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 (see sections 2 and 4).

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of Hydrochlorothiazide 25 Gulf

It is important to take your tablets regularly at the same time each day in order for the desired effects of Hydrochlorothiazide 25 Gulf to be achieved.

If you forget to take a dose, take it as soon as you remember. unless it is time for your next dose. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

Hydrochlorothiazide 25 Gulf can have side effects.

Not all side effects reported for Hydrochlorothiazide 25 Gulf are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Hydrochlorothiazide 25 Gulf, please consult your health care provider for advice.

If any of the following happens, stop taking/giving Hydrochlorothiazide 25 Gulf 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, chest pain, red patches on the skin. This can be an allergic reaction to Hydrochlorothiazide 25 Gulf
- Severe and serious skin reactions which can include:
    - Toxic epidermal necrolysis (Lyell's syndrome) and Steven-Johnson syndrome (SJS) – life-threatening diseases that begin with a fever and flu-like symptoms and then within a few days the skin begins to blister and peel, forming very painful raw areas, called erosions that resemble severe hot-water burns, usually starting on the face and chest before spreading to other parts of the body
    - Systemic lupus erythematosus (SLE) is a condition in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels and can be life-threatening in severe cases (see also section 2)
- Inflammation of blood vessel walls, affecting small and medium blood vessels which interrupt your normal blood flow. It results in skin and muscle damage, including necrosis (necrotizing vasculitis). Necrosis is the death of tissues and organs. The affected blood vessels may be located in any part of your body. The effect of this condition depends on where the affected blood vessels are located and how much damage they cause. You might notice initial symptoms on your own without a medical test. These include chills, fatigue, fever, weight loss. As the disease progresses, symptoms can worsen and become more varied. You may have pain, skin discoloration, lesions, which are usually seen on the legs, ulcers on the skin or genitals, or in the mouth. In some cases, the condition may be limited to your skin. In other cases, you might develop kidney damage or bleeding in your lungs. If your brain is affected, you may have difficulty swallowing, speaking, or moving

- Severe shortness of breath in which you could be unable to breathe on your own without support from a ventilator (respiratory distress) due to the collection of fluid in the air sacs of the lungs which deprives organs of oxygen. This condition can be fatal, the risk increasing with age and severity of illness.

These are very serious side effects. If you have them, you may have had a serious reaction to Hydrochlorothiazide 25 Gulf. 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:

- Skin and lip 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) (see section 2)
- Changes in the blood cells (e.g., reduction in white and red blood cells), resulting in feeling weak, tired or listless, pale skin, and experiencing more frequent and recurrent infections such as fever or sore throat
- Harmful changes in the fat in your blood called cholesterol and triglycerides
- Prolonged or excessive bleeding which can include nosebleeds, bleeding gums, bruising due to low levels of platelets in your blood (thrombocytopenia) which in severe cases can cause dangerous internal bleeding
- Purple-coloured spots that are most recognizable on the skin, but may also appear on organs or mucous membranes, including the membranes on the inside of the mouth (purpura). These purple spots occurs when small blood vessels burst, causing blood to pool under the skin. This can create purple spots on the skin that range in size from small dots to large patches

- Allergic reactions such as skin rashes and asthma
- Low sodium concentration in your blood that can cause neurologic symptoms ranging from confusion, irritability, disorientation in mild cases to seizures (fits), brain swelling and coma in serious cases which can be life-threatening (hyponatraemia) (see section 2)
- Low levels of potassium in your blood (hypokalaemia), which can result in fatigue, muscle cramps and abnormal heart rhythms (see section 2)
- Confusion which can progress to a state of state of near-unconsciousness or insensibility or complete unconsciousness, shaking of your hands, dizziness, muscle twitching, nausea, vomiting, numbness or tingling in the face, hands, or feet and prolonged muscle spasms (tetany) – these are symptoms caused by a condition where the pH of tissue is elevated beyond the normal range (metabolic alkalosis) (see section 2)
- Excessive thirst, frequent urination. upset stomach, nausea, vomiting, constipation. bone pain. muscle weakness, confusion, feeling very tired and having very fast heartbeats (palpitations) and other changes in the way your heart beats which are symptoms of having too much calcium in your blood (hypercalcaemia) (see section 2)
- Shaking, muscle spasms, muscle cramps and/or numbness in your hands and feet, abnormal eye movements (nystagmus), fatigue and weakness, fits, confused thinking and a lack of awareness of your surroundings (delirium) and abnormal heart rhythms (dysrhythmia) which are symptoms related to low magnesium levels in your blood (hypomagnesaemia) (see section 2)
- Disturbances of the amount of different salts in your body (electrolyte imbalances), decrease in chloride in the blood, low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma and may occur in patients with severe heart problems who have swelling due to retained fluid, especially with large doses of Hydrochlorothiazide 25 Gulf in conjunction with restricted salt in the diet (see section 2)
- Fits (convulsions or seizures)
- Sudden blurry vision when looking at distant objects and difficulty seeing objects (acute

myopia) or raised pressure in the eye with symptoms such as severe eye pain, blurred vision, tears, nausea, vomiting and headache (secondary acute angle-closure glaucoma) or 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)

- Improper beating of the heart, whether irregular, too fast or too slow (cardiac dysrhythmias)
- Inflammation of the lungs or difficulty in breathing
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- Liver problems with symptoms such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine (jaundice)
- Kidney problems which can include pain and swelling in your flank, lower back, feet and ankles, problems with your urine, difficulty passing urine, passing more or less urine than usual, reduced excretion of calcium through your kidneys.

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

- Decreased appetite
- High blood sugar (hyperglycaemia) 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.

Less frequent side effects

- Restlessness
- Mental and physical sluggishness (lethargy), drowsiness
- Headache, dizziness
- Burning or prickling sensation (pins and needles) that is usually felt in the hands, arms, legs, or feet (paraesthesia)
- Yellow and/or blurred vision
- A fall in blood pressure on standing up which causes dizziness or fainting (postural hypotension)
- Stomach and intestine complaints and irritation, dry mouth, nausea, vomiting, constipation, diarrhoea
- A sore or ulcer that develops on the lining of the food pipe (oesophagus), stomach or small intestine (intestinal ulceration) with symptoms such as pain in the upper part of the stomach
- Rash, itchy, raised, red or skin-coloured welts or hives on the skin's surface (urticaria)
- Red, itchy patches on your skin when you have been outside (even on a cloudy day) due to skin’s overreaction to sunlight (photosensitivity reaction)
- Muscle pain and cramps, muscle spasm
- Loss of male sexual ability (impotence)
- Thirst, weakness and fever (high temperature).

Side effects occurring with frequency unknown

- Infection of salivary glands (sialadenitis)
- Depression, a mood disorder that causes a persistent feeling of sadness or worthlessness and loss of interest
- Difficulty to sleep
- Feeling unsteady or giddy (vertigo)

- Stomach and intestinal cramps
- Hair loss or baldness (alopecia).

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

By reporting side effects, you can help provide more information on the safety of Hydrochlorothiazide 25 Gulf.

5. How to store Hydrochlorothiazide 25 Gulf

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool, dry place.
- Protect from light and moisture.
- Keep HDPE/PP containers tightly closed.
- Do not remove tablets from container/blister strips until required for use.
- Do not remove tablets from patient ready packs until required for use.
- Keep in the original packaging until required for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the container or label.

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 Hydrochlorothiazide 25 Gulf contains

- The active substance is 25 mg of hydrochlorothiazide.
- The other ingredients are:

  Colloidal silicon dioxide

  Crospovidone

  Microcrystalline cellulose

  Lactose anhydrous

  Magnesium stearate

  Pregelatinised starch

  Purified water.

What Hydrochlorothiazide 25 Gulf looks like and contents of the pack

White to off-white, round shaped, biconvex, uncoated tablet with a central break line on one side and plain on the other side.

The break line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

Clear, push-through PVC/Al blister strips of 10 or 14 tablets each, packed into a unit-carton containing 14, 28 or 30 tablets.

White plastic HDPE/PP containers of 28, 30, 100 or 500 tablets.

Printed patient ready LDPE packs of 28 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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4300

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