SCHEDULING STATUS: S5

GULF AMITRIPTYLINE 25 film-coated tablets
Amitriptyline hydrochloride
Contains sugar: Lactose monohydrate 72,5 mg/tablet

Read all of this leaflet carefully before you start taking GULF AMITRIPTYLINE 25

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

1. What GULF AMITRIPTYLINE 25 is and what it is used for

GULF AMITRIPTYLINE 25 belongs to a class of medicines called tricyclic antidepressants.
GULF AMITRIPTYLINE 25 is used to treat:

- Depression in adults (major depressive episodes)
- Bed-wetting at night in children over 11 years of age, only when organic causes, such as spina bifida and related disorders, have been excluded and no response has been achieved to all other non-medicinal and medicine treatments, including muscle relaxants and desmopressin.

2. What you need to know before you take GULF AMITRIPTYLINE 25

Do not take GULF AMITRIPTYLINE 25:

- If you are hypersensitive (allergic) to amitriptyline or any of the other ingredients of GULF AMITRIPTYLINE 25 (listed in section 6).

- If you have recently had a heart attack (myocardial infarction) or have heart problems such as irregular heartbeats, heart block or failure, coronary artery disease.
- For the treatment of depression in children and adolescents below the age of 18 years.
- If you are taking medicines known as monoamine oxidase inhibitors (MAOIs) used to treat depression, panic disorder, and social anxiety. as well as other nervous system disorders such as Parkinson's disease or if you have taken MAOIs within the last 14 days (see sections "Warnings and precautions" and "Other medicines and GULF AMITRIPTYLINE 25").
- If you are taking the antibiotic, linezolid.
- If you are taking antihypertensive medicine for reducing high blood pressure (see sections "Warnings and precautions" and "Other medicines and GULF AMITRIPTYLINE 25").
- If you are pregnant or breastfeeding your baby.
- If you have a severe liver disease.
- If you suffer from a mental illness marked by periods of great excitement or euphoria, delusions, and overactivity (mania).

Warnings and precautions

Take special care with GULF AMITRIPTYLINE 25:

GULF AMITRIPTYLINE 25 should at all times be kept out of the reach of children, as even small doses may be fatal to them.

- You may experience a dry mouth, constipation, less frequent urination, blurred vision and visual disturbances. If this occurs, discontinue use or seek advice from your healthcare professional regarding reducing the dose.
- GULF AMITRIPTYLINE 25 may make you very drowsy. When therapy starts, you must not drive a motor vehicle, climb dangerous heights or operate dangerous machinery for at least several days as GULF AMITRIPTYLINE 25 can impair your decision making and could lead to accidents due to drowsiness or excessive sedation. You may also experience disorientation, agitation, sleeplessness and restlessness especially when taken with other medicine which can influence the central nervous system – i.e. alcohol and barbiturates (treatments for anxiety and sleeplessness).
- If you are an elderly patient, you are more likely to suffer from certain side effects, such as dizziness when you stand up due to low blood pressure, and you can be especially sensitive to the side effects of GULF AMITRIPTYLINE 25 and therefore you should take a lower dose. In addition, if you suffer from an enlarged prostate, you may experience a

condition in which your bladder doesn't empty completely even if it's full and you often feel like you really have to urinate.

- If you have a manic-depressive illness, characterised by profuse and rapidly changing ideas, exaggerated cheerfulness and excessive physical activity, you may enter into a manic phase. In such cases, it is important to contact your doctor who probably will change your medicine.
- If you suffer from heart rhythm problems and low blood pressure (hypotension) or if you have pre-existing heart disease, you may experience changes in your heart rhythm and blood pressure if you take usual or a high dosage of GULF AMITRIPTYLINE 25. Your doctor may perform regular heart examinations (such as electrocardiographic tests).
- If you have a heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG - a medical test that records the electrical activity of the heart) and heart rhythm disorders (rapid or irregular heartbeat), you must tell your doctor if you:
  - have slow heart rate
  - have or had a problem where your heart cannot pump the blood round your body as well as it should (a condition called heart failure)
  - are taking any other medicines that may cause heart problems
  - have imbalances in the levels of essential minerals (electrolytes) in your body such as a low level of potassium or magnesium, or a high level of potassium in your blood.
- You may experience a change in your sex drive, interference with sexual function, if you are male, you may develop breasts, breast enlargements may occur, as well as excessive or inappropriate milk production.
- Your blood sugar levels may change, and you may suffer from a condition where the body retains water instead of excreting it normally in urine, which may interfere with the essential minerals (electrolytes) balance in your body.
- Tell your doctor if you have, or have had in the past, any medical problems, especially if you have:
  - Diabetes as you might need an adjustment of your antidiabetic medicine. Your blood sugar concentrations should be monitored if you are taking any medicine to treat diabetes
  - Epilepsy, a history of convulsions or fits, as your condition may worsen if you take GULF AMITRIPTYLINE 25
  - Narrow angle glaucoma (loss of vision due to abnormally high pressure in the eye), vision problems (near sighed, far sighted)
  - Liver problems as your condition may worsen if you take GULF AMITRIPTYLINE 25

- An over-active thyroid gland or are taking thyroid medicine
- Paranoia, a state of excessive and irrational suspicion or mistrust of others as your condition may worsen if you take GULF AMITRIPTYLINE 25
- Phaeochromocytoma (a rare tumour of the adrenal gland)
- A condition called porphyria (disorders that can cause skin or nerve problems)
- Difficulty in passing urine due to an enlarged prostate
- Urinary problems such as difficulty in passing urine or gastrointestinal problems such as pylorus stenosis (narrowing of the gastric outlet), constipation and paralytic ileus (blocked intestine)
- Are undergoing electroconvulsive therapy also known as shock therapy, which is a medical procedure used to treat severe mental health conditions, particularly depression and bipolar disorder, when other treatments haven't been effective.

- You may develop low sodium levels in your blood which is characterised by drowsiness, confusion or fits. If you are elderly, you are more prone to develop these effects.
- If you develop an allergic skin reaction, discontinue use.
- If you have a surgery planned, it might be necessary to stop your treatment with GULF AMITRIPTYLINE 25 before you are given anaesthetics. In the case of acute surgery, you must inform the anaesthetist about your treatment with GULF AMITRIPTYLINE 25.
- If you are depressed, you can sometimes have thoughts of harming or killing yourself. These feelings may be increased when first starting antidepressants such as GULF AMITRIPTYLINE 25, since these medicines all take time to work, usually about two weeks but sometimes longer.

  You may be more likely to think like this:
  - If you have previously had thoughts about killing or harming yourself.
  - If you are a young adult as information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

  If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.
- You may experience above normal body temperature especially when taken in

combination with medicine called anticholinergics (they help relax the muscles in the airways in treatment of lung disease, they reduce bladder spasms and urge incontinence in an overactive bladder, they help control tremors and other symptoms in Parkinson's disease and they help reduce nausea and vomiting in gastrointestinal disorders) or medicine called neuroleptics (used to manage psychosis), especially in hot weather.

- The use of buprenorphine (a strong opioid medicine used to treat both severe pain and opioid addiction) together with amitriptyline can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and GULF AMITRIPTYLINE 25").
- Serious and a potentially life-threatening skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with amitriptyline treatment. Stop using amitriptyline and seek medical attention immediately if you notice any of the symptoms related to these serious cutaneous reactions described in section 4.
- If you stop taking GULF AMITRIPTYLINE 25 after prolonged use, withdrawal symptoms may occur such as headache, general discomfort, sleeplessness and irritability.
- If you (or your child) are taking GULF AMITRIPTYLINE 25 for bed-wetting the following may be applicable:
    - Your doctor will do an ECG on you (or your child) before starting treatment
    - You (or your child) may develop suicidal thoughts and behaviours during early treatment with antidepressants such as GULF AMITRIPTYLINE 25 for disorders other than depression; you must observe the same precautions if you (or your child) are being treated for enuresis as if you (or your child) are being treated for depression
    - You (or your child) must not take medicine called anticholinergics when you (or your child) are treated for bed-wetting (enuresis).

Other medicines and GULF AMITRIPTYLINE 25

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

- GULF AMITRIPTYLINE 25 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:
    - Monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson's disease). These should not be taken at the same time as

GULF AMITRIPTYLINE 25 (see section 2 “Do not take GULF AMITRIPTYLINE 25” and “Warnings and precautions”)

- Linezolid (an antibiotic used to treat infections) – you may experience restlessness, agitation, anxiety, or even seizures and high blood pressure (hypertension) (see section 2 “Do not take GULF AMITRIPTYLINE 25”)
- Anticholinergic medicines such as certain medicines to treat Chronic Obstructive Pulmonary Disorders (COPD) and asthma (e.g. ipratropium), an overactive bladder (e.g. oxybutynin, solifenacin), Parkinson’s disease (e.g. benztropine, biperiden) and gastrointestinal disorders (e.g. atropine, dicyclomine, loperamide, hyoscyamine and scopolamine)
- Buprenorphine (a strong opioid medicine used to treat both severe pain and opiate drug addiction) - a potentially life-threatening condition called “serotonin syndrome” may develop (see section 4)

- Diuretics (“water tablets” e.g. furosemide) – you may have an increased risk of developing a very sudden and significant drop in blood pressure when you stand up or change to a more upright position (postural hypotension)
- Medicines used to increase dopamine activity in the brain (dopaminergics) and primarily used to treat conditions like Parkinson's disease and restless legs syndrome
- You have an increased risk of developing abnormal heart rhythms originating in the heart's lower chambers (ventricular dysrhythmias) ranging from relatively harmless to life-threatening, if you are taking GULF AMITRIPTYLINE 25 with:
  - Medicines to treat irregular heartbeats (e.g. quinidine, amiodarone, disopyramide, procainamide, propafenone and sotalol)
  - Astemizole and terfenadine (used to treat allergies and hayfever)
  - Medicines used to treat some mental illnesses (e.g. pimozide and sertindole)
  - Cisapride (used to treat certain types of indigestion)
  - Halofantrine (used to treat malaria)
- Methadone (used to treat pain and for treatment of opiate drug addiction) – you have an increased risk of developing serious cardiovascular side effects
- Sibutramine (used in weight loss) – you have an increased risk of developing serious central nervous system effects
- Adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics)

- Thioridazine (used to treat schizophrenia) – you have an increased risk of developing serious heart side effects

- Tramadol (a strong painkiller) – you have an increased risk to develop fits and serotonin syndrome (see section 4)
- General or local anaesthetics. If you are going to have an operation and receive anaesthetics, you should tell your doctor that you are taking GULF AMITRIPTYLINE 25 as you have an increased risk of developing changes in your heart rhythm or low blood pressure. Likewise, you should tell your dentist that you take GULF AMITRIPTYLINE 25 if you are to receive a local anaesthetic
- Alcohol. You must not drink alcohol during treatment with GULF AMITRIPTYLINE 25 as it might increase the sedative effect
- Phenytoin and carbamazepine (used to treat epilepsy) – you may have an increased risk of the sedative effect
- Some antidepressants called Norepinephrine reuptake inhibitors (NRIs) (e.g. reboxetine)
- Altretamine (used to treat cancer of the ovaries) – you may have a risk of severe postural hypotension
- Nefopam (moderate non-opioid painkiller) and opioids (strong painkillers e.g., morphine, oxycodone, codeine) - you may have an increased risk of sedation
- Ethchlorvynol (used to treat insomnia (trouble in sleeping)) – you may have an increased sedative effect and risk of developing a sudden and often temporary disturbance of mental state characterised by confusion, disorientation, and difficulty concentrating (delirium)
- Baclofen (muscle relaxant)- you may have an enhanced muscle relaxant effect.

- GULF AMITRIPTYLINE 25 can interact with the following medicines to make their effect weaker:
  - Some medicines to treat high blood pressure for example guanethidine, betanidine, debrisoquine, clonidine, reserpine and methyldopa
  - Apraclonidine and brimonidine (medicines used to lower pressure in the eye)
  - Nitrate tablets placed under the tongue, such as glyceryl trinitrate, used to treat angina
  - Neuroleptics (also known as antipsychotic medicines and that are used to manage psychosis, a state of impaired reality perception characterised by delusions,

hallucinations, and disorganised thought) may lead to seizures. Your doctor may adjust the dosage of both the neuroleptic medicine and GULF AMITRIPTYLINE 25.

- Some medicines can interact with GULF AMITRIPTYLINE 25 to make its effect and risk of adverse effects stronger. If you are taking the medicines below, your doctor might monitor you more closely.
  - Medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
  - Disulfiram (medicine used to treat chronic alcoholism) – you may develop delirium
  - Thyroid medication (e.g. Levothyroxine) -you may develop abnormal heartbeats that result from issues with the heart's electrical system
  - Some antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs) (fluoxetine, paroxetine) and bupropion
  - Quinidine (used to manage and treat specific heart rhythm problems and malaria)
  - Fluvoxamine (used to treat obsessive-compulsive disorder (bothersome thoughts that won't go away and the need to perform certain actions over and over) and social anxiety disorder (extreme fear of interacting with others or performing in front of others that interferes with normal life))
  - Ritonavir (used to treat HIV)
  - Cimetidine (used to treat stomach ulcers)
  - Methylphenidate (used to treat ADHD)
  - Some medicines to treat high blood pressure for example calcium-channel blockers (e.g. diltiazem and verapamil)
  - Valproate and valpromide (used in the treatment of epilepsy).

- Some medicines can interact with GULF AMITRIPTYLINE 25 to make its effect weaker:
  - Oral contraceptives (the “pill”)
  - Rifampicin (to treat bacterial infections and is commonly used in combination with other medicine to treat tuberculosis)
  - St. John´s Wort (*hypericum perforatum*) – an herbal remedy used for depression.

GULF AMITRIPTYLINE 25 with food, drink and alcohol

The tablets should be swallowed with a glass of water.

Do not take GULF AMITRIPTYLINE 25 with alcohol as you can have an increased risk of sedation (see section 2 "Driving and using machinery").

Pregnancy, breastfeeding and fertility
You must not take GULF AMITRIPTYLINE 25 if 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 healthcare provider/professional for advice before taking GULF AMITRIPTYLINE 25.

Driving and using machines
It is not always possible to predict to what extent GULF AMITRIPTYLINE 25 may interfere with your daily activities. GULF AMITRIPTYLINE 25 has a major influence on the ability to drive and use machines. GULF AMITRIPTYLINE 25 can cause possible side effects such as drowsiness, dizziness and blurred vision.

At the time of starting your therapy with GULF AMITRIPTYLINE 25, you should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., drive a motor vehicle, climb dangerous heights, operate dangerous machinery or perform any tasks that require concentration, for at least several days until you are aware of the measure to which GULF AMITRIPTYLINE 25 affects you (see section 4). In these situations, impaired decision making could lead to accidents. When GULF AMITRIPTYLINE 25 is taken with alcohol, barbiturates, opioids or other antihypertensives, it increases the risk of postural hypotension.

GULF AMITRIPTYLINE 25 contains lactose monohydrate
GULF AMITRIPTYLINE 25 contains 72,5 mg lactose monohydrate (milk sugar) per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GULF AMITRIPTYLINE 25.

3. How to take GULF AMITRIPTYLINE 25
Do not share medicines prescribed for you with any other person.
Always take GULF AMITRIPTYLINE 25 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Depression

The recommended initial dose is 25 mg three times daily. Depending on the response to the medicine, your doctor may gradually increase the dose to 150 mg per day.
As with other medicines for the treatment of depression it may take a few weeks before you feel any improvement.
In treating depression, the duration of treatment is individual, and is usually at least 3 months before treatment is gradually withdrawn. The duration of treatment is decided by your doctor.

If you are being treated for depression in hospital, you may receive a dose of 200 mg daily, and occasionally up to 300 mg daily.

Children

Enuresis (Bed-wetting at night)

The recommended dose for treatment of bed-wetting is:
Children 11 to 16 years: 25 to 50 mg at bedtime.
Do not exceed the recommended dose.
GULF AMITRIPTYLINE 25 is not suitable for children under 11 years of age.

Treatment should not be continued for more than 3 months and should be withdrawn gradually.
The effects of long-term treatment with GULF AMITRIPTYLINE 25 on growth and development in children has not been established.

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

Special populations

Elderly patients and adolescents

If you are an elderly or adolescent patient, you may be more prone to experience side effects, and your dose may therefore be reduced.

Patients with kidney disease

If you have kidney disease, your dose do not need to be reduced and you can take the usual dose.

Patients with liver disease

If you have severe liver disease should not take GULF AMITRIPTYLINE 25. If you have mild to moderate liver disease you must take GULF AMITRIPTYLINE 25 under medical supervision and usually receive lower doses. Your doctor may take blood samples to determine the level of amitriptyline in your blood (see also section 2 “Do not take GULF AMITRIPTYLINE 25).

Poor metabolisers of CYP2D6 or CYP2C19

If you are a poor metaboliser of CYP2D6 or CYP2C19, you will need to take a reduced dose of GULF AMITRIPTYLINE 25 as you may have higher blood levels of amitriptyline and its active metabolite nortriptyline and therefore be more likely experience side effects.

Method of administration

GULF AMITRIPTYLINE 25 tablets must be taken by mouth with a drink of water.

If you take more GULF AMITRIPTYLINE 25 than you should

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

Symptoms of overdose may include:

- dilated pupils
- difficulty urinating
- dry mouth and tongue
- intestinal blockage
- fits
- fever or shivering
- agitation
- confusion
- seeing, hearing, smelling, tasting, or feeling things that seem real but are not actually present (hallucinations)
- uncontrolled movements
- weak pulse, an abnormal paleness of the skin or mucous membranes (pallor), difficulty breathing
- blue discolouration of the skin

- decreased heart rate
- drowsiness
- loss of consciousness or a state of deep unconsciousness where a you will be unresponsive and cannot be awakened (coma)
- various heart-related symptoms such as low blood pressure, high blood pressure, fast or irregular heartbeats, heart block, heart failure, a life-threatening condition where the heart is unable to pump enough blood to meet the body's needs, leading to a critical lack of oxygen-rich blood reaching vital organs (cardiogenic shock)
- a condition where there is too much acid in the body fluids, typically the blood (metabolic acidosis)
- a condition with low potassium levels in the blood (hypokalemia) which can cause symptoms such weakness, fatigue, muscle cramps, irregular heartbeats, and constipation.

Overdose with GULF AMITRIPTYLINE 25 in children could have serious consequences. Children are especially susceptible to deep unconsciousness (coma), heart symptoms, difficulty in breathing, fits, low blood sodium level, a state of sluggishness, drowsiness, and a general lack of energy (lethargy), drowsiness, nausea, vomiting and high blood sugar level.

If you forget to take GULF AMITRIPTYLINE 25

If you forget to take GULF AMITRIPTYLINE 25, take it as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking GULF AMITRIPTYLINE 25

Your doctor will decide when and how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (e.g. nausea, chills, headache, itching, sweating, anxiety, agitation, feeling unwell, irregular heartbeats, sleeplessness and irritability). Treatment for depression and bedwetting should be withdrawn gradually to reduce the risk of withdrawal symptoms. Talk to your doctor before you stop taking GULF AMITRIPTYLINE 25 and follow their advice to avoid experiencing these withdrawal symptoms.

4. Possible side effects

GULF AMITRIPTYLINE 25 can have side effects.

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

If any of the following happens, stop taking GULF AMITRIPTYLINE 25 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, tongue, 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 GULF AMITRIPTYLINE 25
- The unexpected and swift cessation of heart activity, characterised by the sudden loss of blood flow and breathing, often triggered by a life-threatening heart rhythm disorder resulting in death (sudden cardiac death (SCD))
- Severe and serious skin reactions which can include:
    - A serious drug-induced hypersensitivity reaction characterised by a rash, fever, and systemic organ involvement, often with swollen lymph nodes and high white blood cell counts (Drug reaction with eosinophilia and systemic symptoms (DRESS)). Symptoms can include a rash that may start as small, flat or slightly raised spots, facial swelling, dry lips, and inflammation of organs like the liver or kidneys.

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

- Bruising, bleeding, abnormal paleness of the skin or mucous membranes (pallor), or persistent sore throat and fever. These symptoms can be the first signs that your blood or bone marrow may be affected. Effects on the blood could be a decrease in the number of red cells (which carry oxygen around the body), white cells (which help to fight infection) and platelets (which help with clotting)
- 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
- A condition where there is an excess secretion of antidiuretic hormone (ADH), also known as vasopressin from the pituitary gland causing the body to retain too much water and leading to a dilution of blood sodium levels (hyponatremia)
- 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)
- A period of abnormally elevated, uninhibited, or irritable mood and persistently increased activity or energy, talkativeness, and reduced need for sleep lasting at least one week (mania) (see section 2)
- Thoughts of self-harm or ending your life (see section 2)
- Fits (convulsions or seizures)
- Abnormal changes in the brain's electrical activity, as measured by an electroencephalogram (EEG)
- A state of state of near-unconsciousness or insensibility (confusion) or complete unconsciousness (coma)
- Involuntary movements, muscle stiffness, tremors, and other motor impairments
- Feeling of inner restlessness and a compelling need to be in constant motion
- Attacks of intermittent blurring of vision, rainbow vision, eye pain. You should immediately have an eye examination before the treatment with this medicine can be continued. This condition may be signs of acute glaucoma
- Heart attack, drooping face, arm weakness and slurred speech (stroke), heart block, worsening of cardiac failure, heart muscle disease
- Changes in the way your heart beats, for example, if you notice it is beating faster or experience uneven heartbeat (palpitations), increased, irregular or fast heartbeat (tachycardia), unusually fast or irregular heartbeat (torsades des pointes)
- Bad constipation, a swollen stomach, fever and vomiting (these symptoms may be due to parts of the intestine becoming paralysed)
- Hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver function (clay coloured stool, dark urine, itching, loss of appetite)
- Bones more fragile and susceptible to break

- Problems with urination like the accidental loss of bladder control (urinary incontinence), the inability to completely or partially empty the bladder when urinating (urinary retention), and difficulty with urination
- The body's core temperature rising above its normal range (37 °C), typically above 37,8 °C.

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

- Aggression
- A sudden change in mental function, often accompanied by reduced attention, difficulty focusing, and disorientation. If you are elderly, you may be more prone to develop these side effects
- Feeling irritable, restless, and uneasy
- Feeling very sleepy
- Involuntary, rhythmic shaking or trembling movement of the body (tremors)
- Dizziness
- Headache
- Drowsiness or excessive sedation
- Speech disorders leading to slurred or weak speech (dysarthria)
- Disturbance in attention
- Tingling, prickling, burning, or numbness, often described as "pins and needles," on or just beneath the skin (paraesthesia)
- Loss of muscle coordination, leading to clumsy, unsteady movements (ataxia)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Blocked nose
- Dry mouth
- Constipation
- Nausea
- Sour or metallic taste
- Inflammation or irritation of the stomach lining
- Excessive sweating
- Sexual disturbances (decreased sex-drive, problems with erection)
- Fatigue

- Feeling thirsty
- Abnormal electrocardiogram (ECG) results
- Abnormally low sodium levels in the blood.

Less frequent side effects

- High or low blood sugar, where the level of glucose (sugar) in the blood is above or below the normal range
- Decreased or increased appetite, weight gain or loss, lack of appetite
- Anxiety
- Sleep disturbances (insomnia)
- Nightmares
- Seeing, hearing, smelling, tasting, or feeling things that are not actually present (hallucinations)
- Struggling to concentrate
- Disorientation
- Excitement
- Restlessness
- Struggling to concentrate
- Changes in behaviour
- Movement disorders, numbness, burning pain
- Weakness, numbness, tingling, and pain, often in the hands and feet
- Lack of coordination
- Involuntary, rhythmic shaking or trembling movement of a part of the body (tremor)
- Ringing in the ear
- High blood pressure
- Fainting
- Inflammation of the small air sacs in the lung and of the lungs which can cause shortness of breath, cough, and fatigue
- Stomach and intestine complaints and irritation, dry mouth, nausea, vomiting, constipation, diarrhoea
- A noticeable change in texture, colour, or feeling (rash)
- A skin reaction that causes raised, itchy, and often red or skin-coloured welts or patches on the skin (hives/urticaria)
- Hair loss (alopecia)
- An abnormal or exaggerated skin reaction to sunlight or ultraviolet (UV) light

(photosensitivity reaction)
- Males may develop breasts, breast enlargements may occur, as well as excessive or inappropriate milk production
- Males may develop enlargement of the sac that contains the testicles
- Fever
- Weakness
- Abnormal liver function tests with increase in some liver enzymes.

Side effects occurring with frequency unknown
- A state of mind where you have an exaggerated and persistent feeling of distrust and suspicion towards others, often believing that they are plotting against or trying to harm you (paranoia)
- Dry eye
- Itchiness.

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 GULF AMITRIPTYLINE 25.

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

5. How to store GULF AMITRIPTYLINE 25
Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Keep HDPE containers and/or patient ready packs (PRPs) containers tightly closed.
- Do not remove tablets from container/blister strips/PRPs until required for use.
- Do not use after the expiry date stated on the container/blister strips/PRPs 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 GULF AMITRIPTYLINE 25 contains

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

  Tablet core

  Colloidal silicon dioxide
  Lactose monohydrate
  Magnesium stearate
  Maize starch
  Purified talc

  Film-coating

  Opadry II Yellow (85F32568)
  Purified water.

What GULF AMITRIPTYLINE 25 looks like and contents of the pack

Yellow, round, biconvex, film-coated tablet plain on both sides.
Unit carton containing 28, 56 or 84 tablets in clear PVC/silver printed Aluminium blister strips of 14 or 28 tablets each.
White HDPE containers of 100, 500 or 1000 tablets.
Printed LDPE patient ready packs containing 28, 56, 84 or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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