PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

TRAMAZAC CO 37,5, film-coated tablets

Tramadol hydrochloride, paracetamol

Sugar free.

Read all of this leaflet carefully before you start taking TRAMAZAC CO 37,5.

- 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.
- TRAMAZAC CO 37,5 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 TRAMAZAC CO 37,5 is and what it is used for
2. What you need to know before you take TRAMAZAC CO 37,5
3. How to take TRAMAZAC CO 37,5
4. Possible side effects
5. How to store TRAMAZAC CO 37,5
6. Contents of the pack and other information.

1. What TRAMAZAC CO 37,5 is and what it is used for

Tramadol and paracetamol are the active substances in TRAMAZAC CO 37,5. They are painkillers that act on the brain and spinal cord to control pain. TRAMAZAC CO 37,5 is used for the management of moderate to moderately severe pain in adults.

2. What you need to know before you take TRAMAZAC CO 37,5

Do not take TRAMAZAC CO 37,5

- If you are hypersensitive (allergic) to tramadol, paracetamol, other opioids such as codeine, or any of the other ingredients of TRAMAZAC CO 37,5 (listed in section 6).
- If you have drunk enough alcohol to make you feel woozy or drunk.
- If you have taken more than the prescribed dose of your sleeping tablets, other painkillers or psychotropic medicines (medicines that affect your mood and emotions), which can slow down your breathing and reactions.
- If you have a moderate to severe liver disease.
- If you are taking monoamine oxidase (MAO) inhibitors (medicine used to treat depression) or have taken them in the last 14 days before treatment with TRAMAZAC CO 37,5 (see **Other medicines and TRAMAZAC CO 37,5**).
- You should not receive TRAMAZAC CO 37,5 for the treatment of withdrawal symptoms caused by narcotics/drugs.
- If you have problems to breathe, if you have a bluish discolouration of your skin (due to decreased oxygen) or have excessive mucus.
- If you have growing pressure inside your skull (headache, blurred vision, weakness) or central nervous system depression due to a head injury, a disorder that affect blood supply to your brain.
- If you suffer from epilepsy (fits) or seizures of any cause.
- If you or your child are younger than 12 years of age.
- If you or your child are younger than 18 years of age and you or your child have had an operation to remove your tonsils or adenoids.

Warnings and precautions

Take special care with TRAMAZAC CO 37,5:

- If you are taking medicines which may cause seizures/fits such as neuroleptics/antipsychotics (used to treat depression or a psychotic disorder). The risk of having a seizure/fit may increase if you use TRAMAZAC CO 37,5 at the same time (see **Other medicines and**

TRAMAZAC CO 37,5).

- If you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS), or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with TRAMAZAC CO 37,5 must immediately be discontinued. These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your health care provider immediately.
- If you are taking sedating medicines, also known as central nervous system (CNS) depressants, such as benzodiazepines (used to treat anxiety, panic attacks and insomnia or trouble sleeping) (see **Other medicines and TRAMAZAC CO 37,5**).
- If you have any biliary tract disorder (disorder involving your gallbladder and/or liver with symptoms such as abdominal pain, yellowing of your skin and eyes, nausea, vomiting and fatigue).
- If you are not as awake/alert, or able to understand or react as you normally would, and the cause is uncertain.
- If you are in a state of shock (cold sweat may be a sign).
- If you have any thoughts of harming or killing yourself.
- If you have any liver or kidney problems.
- If you have been using TRAMAZAC CO 37,5 for a long time and have increased pain, contact your doctor.
- If you suffer from a lung disease.
- If you suffer from emotional disturbance or depression.
- Do not take more than your recommended dose.
- Do not take TRAMAZAC CO 37,5 with any other medicines that contain tramadol or paracetamol.

Sleep-related breathing disorders

TRAMAZAC CO 37,5 contains the active substance, tramadol, that belongs to the group of opioids.

Opioids can cause sleep-related breathing disorders, for example central sleep apnoea (shallow/pause in breathing during sleep) and sleep-related hypoxaemia (low levels of oxygen in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. The risk of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your dosage if you experience central sleep apnoea.

Serotonin syndrome

You may experience serotonin syndrome (a serious condition where your body has too much of a chemical called serotonin) after taking TRAMAZAC CO 37,5 in combination with certain antidepressants or TRAMAZAC CO 37,5 alone. Consult your doctor immediately if you have any of the symptoms related to this condition (see section **4. Possible side effects**).

Dependence/addiction and tolerance

TRAMAZAC CO 37,5 may lead to dependence/addiction, especially with long-term use. If you have a history of addiction, especially to medicines of the same class as tramadol (opioids) such as codeine, additional support and monitoring may be necessary.

If you find that treatment with TRAMAZAC CO 37,5 is less effective after long-term use, it could be a sign that you have developed tolerance. If this happens, speak to your doctor about your treatment.

Withdrawal symptoms

You may experience withdrawal symptoms if treatment with TRAMAZAC CO 37,5 is suddenly stopped. Withdrawal symptoms can include agitation, anxiety, difficulty sleeping, restlessness, tremor (uncontrolled shaking) and gastrointestinal (stomach) symptoms.

Your doctor will discuss with you how to gradually reduce your dose of TRAMAZAC CO 37,5

before stopping.

TRAMAZAC CO 37,5 metabolism

Tramadol, as in TRAMAZAC CO 37,5, is metabolised in your liver by an enzyme. Some people have a variation of this enzyme, and this can affect people in different ways. In some people, they may not get enough pain relief but other people, known as ultra-rapid metabolisers, are more likely to get serious side effects (such as breathing difficulties, with slow or shallow breathing, confusion, sleepiness, feeling or being sick, constipation and lack of appetite). If you experience any of these side effects, stop taking TRAMAZAC CO 37,5 and consult your doctor immediately.

Low cortisol levels

Discuss it with your doctor if you experience any of the following symptoms while taking TRAMAZAC CO 37,5: extreme fatigue, decreased appetite, weight loss, severe stomach pain, feeling or being sick or low blood pressure. This may indicate that you have adrenal insufficiency (a disorder in which your adrenal glands don’t produce enough hormones, mainly cortisol). If you have these symptoms, your doctor will decide if you need to take a hormone supplement.

Low sodium levels

You may experience low levels of sodium in your blood (hyponatraemia) while taking TRAMAZAC CO 37,5. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that may lower sodium in the blood are most at risk. If you get any of these symptoms while taking TRAMAZAC CO 37,5, consult your doctor immediately.

Minor pain

You should not take TRAMAZAC CO 37,5 for minor pain that may be adequately treated with other painkillers.

Children and adolescents

- TRAMAZAC CO 37,5 should not be given to children below 12 years of age.
- TRAMAZAC CO 37,5 should not be given for pain to children below 18 years of age with airflow blockage during sleep (obstructive sleep apnoea) after an operation to remove their tonsils or adenoids.
- TRAMAZAC CO 37,5 is not recommended for use in children with breathing problems, including neuromuscular disorders (conditions that impair the functioning of the muscles, either directly or indirectly, through the nervous system), severe heart or lung conditions, lung infections, several serious injuries or major surgery.

Other medicines and TRAMAZAC CO 37,5

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

Tell your doctor or pharmacist if you are currently taking:

- Monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days before treatment with TRAMAZAC CO 37,5 (see **Do not take TRAMAZAC CO 37,5**).
- Sedatives or tranquillisers, also known as central nervous system (CNS) depressants, such as barbiturates and benzodiazepines (used to treat anxiety, panic attacks, insomnia or trouble sleeping).
- Serotonergic medicines (medicines that may increase serotonin levels in your body) such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs) and tricyclic antidepressants (used to treat depression).
- Lithium (used to stabilise your mood).
- Medicines which may cause seizures/fits such as certain antidepressants or antipsychotics (used to treat depression or a psychotic disorder). The risk of having a seizure/fit may increase if you use TRAMAZAC CO 37,5 at the same time (see **Warnings and precautions**).
- Anticoagulants such as warfarin (used to thin your blood). Regular evaluation of your prothrombin time/INR should be performed if you are taking warfarin with TRAMAZAC CO 37,5.

- Medicines which may reduce certain enzymes known as CYP2D6 and CYP3A4 in your body, such as amitriptyline, fluoxetine and paroxetine (used to treat depression), quinidine (used to stabilise your heart rhythm), ketoconazole (used to treat a fungal infection) and erythromycin (used to treat a bacterial infection).
- Medicines which may increase the CYP3A4 enzyme in your body, such as rifampicin (used to prevent and treat tuberculosis) and phenytoin (used to treat and prevent seizures/fits).
- Carbamazepine (used to treat seizures/fits).
- Ondansetron (used to prevent nausea and vomiting).
- Cimetidine (used to treat stomach ulcers or heartburn).
- Diflunisal (used to relieve mild to moderate pain from various conditions. It also reduces pain, swelling and joint stiffness caused by arthritis).
- Metoclopramide (used to treat nausea and vomiting).
- Colestyramine (used to lower high cholesterol levels in the blood).

TRAMAZAC CO 37,5 with alcohol

Do not drink alcohol during treatment with TRAMAZAC CO 37,5 as it may have additive sedative effects.

Pregnancy, breastfeeding and fertility

Safe use in pregnancy and breastfeeding has not been established.

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 TRAMAZAC CO 37,5.

Do not take TRAMAZAC CO 37,5 if you are pregnant or breastfeeding your baby.

Driving and using machines

TRAMAZAC CO 37,5 may cause drowsiness and dizziness and affect your ability to drive a vehicle

or use machinery. This is particularly in conjunction with other medicines that may affect your mental state, behaviour or mood, including alcohol.

It is not always possible to predict to what extent TRAMAZAC CO 37,5 may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which TRAMAZAC CO 37,5 affects you.

3. How to take TRAMAZAC CO 37,5

Do not share medicines prescribed for you with any other person.
Always take TRAMAZAC CO 37,5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For use in adults and children over the age of 16 years.
DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

Tablets are to be taken whole, not broken or chewed, with a sufficient quantity of liquid, with or without meals.

Unless otherwise prescribed by your doctor, the usual dose is:
Adults and children over 16 years:
For the management of pain, the recommended dose is 1 or 2 tablets every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.

The lowest pain-relieving dose should be taken for the shortest period of time.

If you have any liver or kidney problems or are over 65 years of age, your doctor may adjust your dosage.

Your doctor will tell you how long your treatment with TRAMAZAC CO 37,5 will last. If you have the

impression that the effect of TRAMAZAC CO 37,5 is too strong or too weak, tell your doctor or pharmacist.

If you take more TRAMAZAC CO 37,5 than you should

Possible signs and symptoms of overdosage may include narrowing of the pupil of your eye, nausea (feeling sick), vomiting (being sick), fast heartbeat, loss of sufficient blood flow to maintain consciousness due to sudden dysfunction of the heart, heart stops beating, unconsciousness, coma, convulsions (fits), breathing difficulty (slow and ineffective breathing) and stopped breathing, stomach pain, irritation and discomfort in the stomach and gut, unusually pale skin, weight loss and abnormal heavy sweating.

Cases of abnormal electrical conduction in the heart (QT prolongation) as well as serotonin syndrome have also been reported (see section **4. Possible side effects**).

Even if you feel well after having taken more TRAMAZAC CO 37,5 than you should have, you should still seek medical assistance as there is a risk of delayed, serious liver damage.

Immediate treatment is essential. 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 TRAMAZAC CO 37,5

Do not take a double dose to make up for forgotten individual doses. If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your TRAMAZAC CO 37,5 tablets at the next regularly scheduled time.

If you stop taking TRAMAZAC CO 37,5

Treatment with TRAMAZAC CO 37,5 should not be stopped abruptly, as you may experience withdrawal symptoms. If you no longer require treatment or wish to stop treatment due to adverse

effects, please tell your doctor. Your doctor will gradually reduce your dose of TRAMAZAC CO 37,5 before you finally stop taking TRAMAZAC CO 37,5.

If you suddenly stop taking TRAMAZAC CO 37,5, you may experience withdrawal symptoms such as agitation, anxiety, hallucinations, tingling or prickling ("pins-and-needles") sensation, ringing in your ears, restlessness, difficulty sleeping (insomnia), uncontrolled shaking (tremors), increased heart/breathing rate, nausea, vomiting, diarrhoea and stomach cramps.

If you experience any of these symptoms, or any other side effects while stopping treatment with TRAMAZAC CO 37,5, please contact your doctor.

4. Possible side effects

TRAMAZAC CO 37,5 can have side effects.
Not all side effects reported for TRAMAZAC CO 37,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAMAZAC CO 37,5, please consult your health care provider for advice.

If any of the following happens, stop taking TRAMAZAC CO 37,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, wheezing.
- A rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRAMAZAC CO 37,5. 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:

- Serotonin syndrome (agitation, hallucinations, fever, increased heart rate, increased blood

pressure, involuntary muscle twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms, such as nausea, vomiting and diarrhoea).

- Convulsions/fits.
- Changes in the way your heart beats, such as pounding of your heart, beating faster or slower than normal, irregular heartbeat, skipping a beat, chest pain, lack of blood flow through your body (due to cardiac or circulatory collapse) or to your heart muscle.
- Passing less urine than is normal for you or with difficulty/pain, difficulty in emptying your bladder completely (urinary retention), excess protein in your urine (frequent urination, foamy/bubbly urine), kidney damage (swelling of your hands, feet and face, nausea, weakness), ureteral or biliary spasms (burning or cramping pain in your stomach).
- Slow/ineffective breathing, shortness of breath, excess fluid in your lungs (difficulty breathing, cough), worsening of asthma.
- Yellowing of your skin and eyes, dark urine, fever and tiredness, which may be symptoms of liver problems such as increased liver enzymes.
- Skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain (see **Take special care with TRAMAZAC CO 37,5**).
- Medicine abuse/dependence, withdrawal reactions (see **If you stop taking TRAMAZAC CO 37,5**).
- Low blood levels of sodium (tiredness, confusion, muscle twitching, nausea, headache) and/or syndrome of inappropriate antidiuretic hormone secretion (cramping, nausea, vomiting, and in severe cases, seizures and coma).
- Stomach pain including inflammation of your pancreas (pain of the upper stomach area that radiates to your back, tenderness, nausea, vomiting, fever).
- Dark black, tarry stool with or without visible blood (may be associated with bleeding in your digestive tract).

- A unique allergic skin reaction that often occurs in the same location after re-exposure to a medicine (known as fixed drug eruption).
- Thoughts of harming or killing yourself.
- Growing pressure inside your skull (headache, blurred vision, weakness).
- Anaemia (a condition in which your body does not have enough healthy red blood cells, with symptoms such as extreme tiredness, pale skin, shortness of breath, dizziness).

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:

- Drowsiness, dizziness, headache, uncontrolled shaking (tremors).
- Nausea (feeling sick), vomiting (begin sick), dry mouth, heartburn, constipation, diarrhoea, stomach pain, excess gas (flatulence).
- Increased sweating.
- Skin itching/rash.
- Fatigue (extreme tiredness / lack of energy), physical weakness.
- Changes in your mood (mostly feeling happy, occasionally irritated/unhappy).
- Feeling confused, sleep disorders (difficulty falling/staying asleep), feeling anxious, nervousness.
- Anorexia (severe weight loss).

Less frequent side effects:

- Difficulty swallowing, swelling of your tongue.
- Changes in your appetite.
- Decline in mental ability (memory/thinking), difficulty concentrating.
- Hallucinations (seeing or hearing things that are not real), nightmares, abnormal thinking.
- Feeling depressed.
- Feeling disconnected or detached from your body and thoughts.
- Erectile dysfunction (impotence).

- Impaired balance or coordination, increased muscle tone making it hard to flex and move around normally, involuntary muscle contractions, speech disorders.
- Migraines (headache of varying intensity, often accompanied by nausea and sensitivity to light and sound).
- Memory loss.
- Tingling or prickling (“pins-and-needles”) sensation.
- Decreased responsiveness.
- Narrowing or excessive widening of your pupils, blurred vision.
- Spinning sensation, ringing in your ears.
- Increased blood pressure (dizziness, headache).
- Postural hypotension (a form of low blood pressure that happens when standing up from sitting or lying down, which may cause dizziness or light-headedness).
- Hot flushes.
- Raised, itchy rash (urticaria).
- Muscle weakness.
- Cold chills (shivering or shaking), low body temperature.
- Increased creatinine and prothrombin levels in the blood when tests are done.
- Changes in your white/red blood cells or platelet count when tests are done.
- Low level of prothrombin in your blood, causing an increased risk of bleeding.

Frequency unknown side effects:

- Low blood sugar levels (light-headedness, tiredness, weakness).
- Restlessness, decreased/increased activity, changes in mental and sensory perception (errors in judgement, changes in senses and recognition), reduced awareness of surroundings.
- Feeling uneasy, unhappy or unwell.
- Widening of your blood vessels, leading to increased blood flow with flushing or warmth.
- Itchy skin rash caused by contact with TRAMAZAC CO 37,5.
- Muscle stiffness, movement disorders.
- Decreased interest in sexual activity.

- Hiccups.
- Changes in the effects of blood thinners (such as warfarin) including an increase in prothrombin time, causing an increased risk of bleeding.

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 doctor or pharmacist. 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

By reporting side effects, you can help provide more information on the safety of TRAMAZAC CO 37,5.

5. How to store TRAMAZAC CO 37,5

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a dry place.
- Keep the blister strips in the outer carton until required for use.
- 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 TRAMAZAC CO 37,5 contains

- The active substances are tramadol hydrochloride and paracetamol.

  Each film-coated tablet contains 37,5 mg tramadol (as tramadol hydrochloride) and 325 mg paracetamol.
- The other ingredients are magnesium stearate, maize starch, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate and Opadry White 03F58991 (containing hypromellose, macrogol, talc and titanium dioxide).

What TRAMAZAC CO 37,5 looks like and contents of the pack

White coloured, capsule shaped, bevel edged, biconvex film-coated tablets debossed with “334” on one side and plain on the other side.

White opaque PVDC/PVC/silver aluminium blister strips, containing 10 tablets each. Each outer carton contains 3 or 6 blister strips.

Pack sizes: 30 or 60 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised

01 March 2024

Registration number

45/2.9/0303

Date of registration

20 June 2013