Patient information leaflet for TRAMAZAC 50

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

TRAMAZAC 50, capsules

Tramadol hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking TRAMAZAC 50

- 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 50 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 50 is and what it is used for
2. What you need to know before you take TRAMAZAC 50
3. How to take TRAMAZAC 50
4. Possible side effects
5. How to store TRAMAZAC 50
6. Contents of the pack and other information.

1. What TRAMAZAC 50 is and what it is used for

Tramadol, the active substance in TRAMAZAC 50, is a painkiller belonging to a class of medicines called opioids, that acts on the central nervous system. TRAMAZAC 50 is used for the

management of moderate to moderately severe pain.

2. What you need to know before you take TRAMAZAC 50

Do not take TRAMAZAC 50

- If you are hypersensitive (allergic) to tramadol hydrochloride, other opioid pain-relieving medicines or any of the other ingredients of TRAMAZAC 50 (listed in section 6).
- If you have drunk enough alcohol to make you feel woozy or drunk or 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 are taking monoamine oxidase (MAO) inhibitors (medicine used to treat depression) or have taken them in the last 14 days before treatment with TRAMAZAC 50 (see **Other medicines and TRAMAZAC 50**).
- If you have problems to breathe, if you have a bluish discoloration 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 or a disorder that affect blood supply to your brain.
- 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.
- If you suffer from epilepsy (fits).
- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).
- You should not receive TRAMAZAC 50 for the treatment of withdrawal symptoms caused by narcotics/drugs.

Warnings and precautions

Take special care with TRAMAZAC 50:

- 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 50 at the same time (see **Other medicines and TRAMAZAC 50**).
- If you are in a state of shock (cold sweat may be a sign).
- 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 50**).
- If you are addicted to other opioids, as TRAMAZAC 50 is not a suitable substitute to suppress withdrawal symptoms.
- If you are sensitive to opioid pain relievers.
- If you have any liver or kidney problems.

Sleep-related breathing disorders

TRAMAZAC 50 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 of breathing during sleep) and sleep related hypoxemia (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 50 in combination with certain antidepressants or TRAMAZAC 50 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 50 may lead to dependence/addiction, especially with long-term use. If you have a tendency towards medicine abuse or dependence, you should only use TRAMAZAC 50 for short periods and under strict medical supervision.

If you find that treatment with TRAMAZAC 50 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 50 is suddenly stopped. Withdrawal symptoms can include agitation, anxiety, nervousness, difficulty sleeping, restlessness, tremor (uncontrolled shaking) and gastrointestinal (stomach) symptoms.

Your doctor will discuss with you how to gradually reduce your dose of TRAMAZAC 50 before stopping.

Increased sensitivity to pain

If you have been taking TRAMAZAC 50 for a long time and present with increased pain, consult your doctor for advice.

TRAMAZAC 50 metabolism

Tramadol, as in TRAMAZAC 50, 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 50 and consult with your doctor immediately.

Low cortisol levels

Discuss with your doctor if you experience any of the following symptoms while taking TRAMAZAC 50: 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 50. 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 50, consult with your doctor immediately.

Minor pain

You should not take TRAMAZAC 50 for the treatment of minor pain.

Children and adolescents

- TRAMAZAC 50 should not be given to children below 12 years of age.
- TRAMAZAC 50 should not be given to children below 18 years of age after an operation to remove their tonsils or adenoids for pain or airflow blockage during sleep (obstructive sleep apnoea).
- TRAMAZAC 50 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 50

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 50 (see **Do not take TRAMAZAC 50**).
- 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).
- 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 50 at the same time (see **Warnings and precautions**).
- Anticoagulants such as warfarin (used to thin your blood).
- Medicines which may reduce a certain enzyme known as CYP3A4 in your body such as ketoconazole (used to treat a fungal infection) and erythromycin (used to treat a bacterial infection).
- Carbamazepine (used to treat seizures/fits).
- Ondansetron (used to prevent nausea and vomiting).
- Analgesics, including opioids, such as morphine (used to treat pain).
- Cimetidine (used to treat heartburn and stomach ulcers).

TRAMAZAC 50 with alcohol

Do not drink alcohol during treatment with TRAMAZAC 50 as it may have additive sedative effects.

Pregnancy, breastfeeding and fertility

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 you take TRAMAZAC 50.

Do not take TRAMAZAC 50 if you are pregnant or breastfeeding your baby.

Driving and using machines

TRAMAZAC 50 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 50 may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which TRAMAZAC 50 affects you.

3. How to take TRAMAZAC 50

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

Always take TRAMAZAC 50 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. The lowest pain-relieving dose should be taken.

Do not take more than 400 mg tramadol (equivalent to 8 TRAMAZAC 50 capsules) daily.

Capsules are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

Unless otherwise prescribed by your doctor, the usual dose is:

Adults and children over 12 years:

Moderate pain: Take an initial dose of 50 mg tramadol (1 TRAMAZAC 50 capsule), followed by 50 mg or 100 mg every 4 to 6 hours.

Severe pain: Take an initial dose of 100 mg tramadol (2 TRAMAZAC 50 capsules), followed by 50 mg or 100 mg every 4 to 6 hours.

If you have any liver or kidney problems or are over 75 years of age, your doctor may adjust your dosage.

Your doctor will tell you how long your treatment with TRAMAZAC 50 will last. You should not take TRAMAZAC 50 for longer than is absolutely necessary. If you need to be treated for a longer period, your doctor will check at regular short intervals whether you should continue to take TRAMAZAC 50 and at what dose.

If you have the impression that the effect of TRAMAZAC 50 is too strong or too weak, tell your doctor or pharmacist.

If you take more TRAMAZAC 50 than you should

Possible signs and symptoms of overdosage include narrowing of the pupil of your eye, vomiting (being sick), loss of sufficient blood flow to maintain consciousness due to sudden dysfunction of the heart, unconsciousness, coma, convulsions (fits), restlessness, breathing difficulty (slow and ineffective breathing) and stopped breathing.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining capsules with you, so that the doctor knows what you have taken.

If you forget to take TRAMAZAC 50

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking TRAMAZAC 50

Treatment with TRAMAZAC 50 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 50 before you finally stop taking TRAMAZAC 50. If you suddenly stop taking TRAMAZAC 50, you may experience withdrawal symptoms such as agitation, anxiety, hallucinations, tingling or prickling ("pins-and-needles") sensation, ringing in your ears, confusion, paranoia, nervousness, difficulty sleeping (insomnia), muscle spasms, uncontrolled shaking and upset stomach,

If you experience any of these symptoms, or any other side effects while stopping treatment with TRAMAZAC 50**,** please contact your doctor.

4. Possible side effects

TRAMAZAC 50 can have side effects.

Not all side effects reported for TRAMAZAC 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAMAZAC 50, please consult your health care provider for advice.

If any of the following happens, stop taking TRAMAZAC 50 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, worsening of asthma.
- Rash or itching.

- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRAMAZAC 50. 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 (mainly after administration of high doses or when taken at the same time as other medicines which may cause fits).
- Changes in the way your heart beats, such as pounding of your heart, beating faster or slower than normal, irregular heartbeat or the lack of blood flow through your body (due to cardiac or circulatory collapse).
- Passing urine with difficulty or pain, difficulty in emptying your bladder completely (urinary retention), frequent urination.
- Slow/ineffective breathing, shortness of breath, tightening of your chest which causes wheezing and coughing.
- Yellowing of your skin and eyes, dark urine, fever and tiredness, which may be symptoms of liver problems such as increased liver enzymes.
- Severe forms of skin reactions, sometimes accompanied by fever, causing a painful, blistering or peeling skin rash. These may be signs of a condition known as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN).
- Medicine dependence, withdrawal reactions (see **If you stop taking TRAMAZAC 50**).
- 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).
- Inflammation of your pancreas (upper stomach pain, nausea, vomiting, fever).

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:

- Sedation, drowsiness, dizziness, headache.
- Nausea (feeling sick), vomiting (begin sick), dry mouth, heartburn, constipation, diarrhoea, stomach pain.
- Increased sweating.
- Fatigue (constant tiredness or weakness).
- Anorexia (severe weight loss).

Less frequent side effects:

- Changes in your appetite.
- Hallucinations (seeing or hearing things that are not real), feeling confused, reduced awareness of surroundings, sleep disturbances, feeling anxious, nightmares.
- Changes in your mood (mostly feeling happy, occasionally irritated/unhappy), decreased activity, restlessness, changes in mental and sensory perception (errors in judgement, changes in senses and recognition).
- Speech disorders, memory loss, uncontrolled shaking (tremor), involuntary muscle contractions, uncoordinated movement.
- Tingling or prickling (“pins-and-needles”) sensation.
- Narrowing or excessive widening of your pupils, blurred vision.
- 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).
- Flushing (reddening of your face, neck or upper chest).
- Gagging (retching), stomach discomfort.
- Blisters (fluid-filled sac in the outer layer of your skin).

- Raised, itchy rash (urticaria).
- Weak muscles.

Frequency unknown side effects:

- Low blood sugar levels (light-headedness, tiredness, weakness).
- Hiccups.

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 50.

5. How to store TRAMAZAC 50

- Store all medicines out of reach of children.
- Store at or below 25 ºC.
- Store in a dry place.
- Protect from light.
- Keep blister strips in 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 50 contains

- The active substance is tramadol hydrochloride.

  Each capsule contains 50 mg tramadol (as tramadol hydrochloride).

- The other ingredients are dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and the capsule shell (containing brilliant blue, gelatine, quinoline yellow and titanium dioxide).

What TRAMAZAC 50 looks like and contents of the pack

TRAMAZAC 50 is a size 2 locked hard gelatine capsule with a green cap and green body, containing white to off-white powder.

TRAMAZAC 50 capsules are packed in clear PVC/PVdC and printed aluminium foil blister strips containing 10 or 20 capsules packed in an outer carton containing 20, 100 or 140 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, G/Floor

22 Karee Street

Centurion 0157

Tel: 012 748 6400

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