PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

TRAMAZAC SR 100 / 150 / 200, film-coated tablets

Tramadol hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking TRAMAZAC SR.

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

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

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

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

Do not take TRAMAZAC SR

- If you are hypersensitive (allergic) to tramadol hydrochloride, other opioid pain-relieving medicines or any of the other ingredients of TRAMAZAC SR (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 SR (see **Other medicines and TRAMAZAC SR**).
- 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, or previously had a stroke.
- 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**).
- If you or your child are younger than 12 years of age.
- You should not receive TRAMAZAC SR for the treatment of withdrawal symptoms caused by narcotics/drugs.

Warnings and precautions

Take special care with TRAMAZAC SR:

- 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 SR at the same time (see **Other medicines and TRAMAZAC SR**).

- 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 SR**).
- 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 addicted to other opioids, as TRAMAZAC SR is not a suitable substitute to suppress withdrawal symptoms.
- If you have any thoughts of harming or killing yourself.
- If you are sensitive to opioid pain relievers.
- If you have any liver or kidney problems.
- If you suffer from a lung disease, including asthma.
- If you have an underactive thyroid, an enlarged prostate (with symptoms such as urination difficulty), low blood pressure, disorder of your intestines causing inflammation (pain and swelling) or blockage, or myasthenia gravis (a long-term condition that causes weakness of your muscles).

Sleep-related breathing disorders

TRAMAZAC SR 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 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 SR in combination with certain antidepressants or TRAMAZAC SR 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 SR 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 SR for short periods and under strict medical supervision.

If you find that treatment with TRAMAZAC SR 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 SR 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 SR before stopping.

History of mental health disorders

TRAMAZAC SR should be used with particular care if you or any member of your family had mental health problems in the past, characterised by a persistently low or depressed mood (major depression), feeling of fear or worry (anxiety), or the misuse of alcohol and drugs.

Increased sensitivity to pain

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

TRAMAZAC SR metabolism

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

Low cortisol levels

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

Minor pain

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

Children and adolescents

- TRAMAZAC SR should not be given to children below 12 years of age.

- TRAMAZAC SR 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 SR 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 SR

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 SR (see **Do not take TRAMAZAC SR**).
- 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 SR at the same time (see **Warnings and precautions**).
- Anticoagulants such as warfarin (used to thin your blood).
- Medicines which may reduce certain enzymes known as CYP2D6 and CYP3A4 in your body, such as amitriptyline, fluoxetine and paroxetine (used to treat depression), 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 St John’s wort (an herbal supplement that may assist with

symptoms of depression).

- Carbamazepine (used to treat seizures/fits).
- Ondansetron (used to prevent nausea and vomiting).
- Cimetidine (used to treat heartburn and stomach ulcers).
- Analgesics, including opioids such as morphine (used to treat pain).

TRAMAZAC SR with alcohol

Do not drink alcohol during treatment with TRAMAZAC SR 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 taking TRAMAZAC SR.

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

Driving and using machines

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

3. How to take TRAMAZAC SR

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

Always take TRAMAZAC SR 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 daily.

Tablets are to be taken whole, not divided or chewed, with sufficient liquid, with or without meals.

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

Adults and children over 12 years:

The usual initial dose is 100 mg twice daily, preferably in the mornings and evenings.
If pain relief is not adequate, the dose may be increased to 150 mg or 200 mg twice daily.
Dosage intervals should be at least 8 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 SR will last. You should not take TRAMAZAC SR 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 SR and at what dose.

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

If you take more TRAMAZAC SR than you should

Possible signs and symptoms of overdosage include narrowing of the pupil of your eye, vomiting (being sick), slow heartbeat, low blood pressure, loss of sufficient blood flow to maintain consciousness due to sudden dysfunction of the heart, weakness, unconsciousness, coma,

convulsions (fits), cold clammy skin, dizziness, breakdown of muscle tissue that releases a damaging protein into your blood which may damage your kidneys (symptoms include dark, reddish urine, a decreased amount of urine, weakness and muscle aches), breathing difficulty (slow and ineffective breathing) and breathing that stopped.
Serotonin syndrome has also been reported (see section 4 – **Possible side effects**).

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 tablets with you, so that the doctor knows what you have taken.

If you forget to take TRAMAZAC SR

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

If you stop taking TRAMAZAC SR

Treatment with TRAMAZAC SR 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 SR before you finally stop taking TRAMAZAC SR. If you suddenly stop taking TRAMAZAC SR, 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 SR, please contact your doctor.

4. Possible side effects

TRAMAZAC SR can have side effects.

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

If any of the following happens, stop taking TRAMAZAC SR 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.
- Rash or itching.
- Fainting.
- Heart attack.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRAMAZAC SR. 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, chest pain 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 or blood in your urine.
- Slow/ineffective breathing, shortness of breath, tightening of your chest which causes wheezing and coughing, 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.

- 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).
- Bacterial skin infection known as cellulitis (swollen, red skin that may be hot and tender).
- Medicine dependence, withdrawal reactions (see **If you stop taking TRAMAZAC SR**).
- 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 appendix (nausea, vomiting, fever, pain on lower right area of your stomach), gallbladder inflammation (severe pain in the upper right portion of your stomach and bloating), gallstones (sudden and rapidly intensifying pain in the upper right portion of your stomach, back pain, nausea or vomiting).
- Stomach pain, including pancreas inflammation (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 (extreme tiredness, lack of energy)
- Anorexia (severe weight loss).
- Abnormal physical weakness, flu-like illness (fever, cough, sore throat, runny nose, body aches).
- Feeling depressed.
- Spinning sensation, feeling confused and unable to think clearly.

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/agitated, nightmares.
- Changes in your mood (mostly feeling happy, occasionally irritated/unhappy), decreased/increased activity, restlessness, nervousness, 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, walking abnormal/unusual.
- Reduced touch sensitivity (numbness).
- 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).
- Runny/stuffy nose.
- Gagging (retching), bloating.
- Blisters (fluid-filled sac in the outer layer of your skin).
- Raised, itchy rash (urticaria).
- Skin inflammation/irritation (itchy, dry skin or rash).
- Muscle weakness or pain.
- Joint pain, stiffness or swelling, back pain.
- Cold chills (shivering or shaking).

Side effects that occur with unknown frequency :

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

- Upper respiratory tract infection such as bronchitis (cough, production of mucus, shortness of breath, fever).

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 SR.

5. How to store TRAMAZAC SR

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strips in the outer carton until required for use.
- Do not use after the expiry date printed on the packaging.
- 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 SR contains

- The active substance is tramadol hydrochloride.

  Each TRAMAZAC SR 100 tablet contains 100 mg tramadol (as tramadol hydrochloride).

  Each TRAMAZAC SR 150 tablet contains 150 mg tramadol (as tramadol hydrochloride).

  Each TRAMAZAC SR 200 tablet contains 200 mg tramadol (as tramadol hydrochloride).

- The other ingredients are magnesium stearate, microcrystalline cellulose, polyethylene oxide,

povidone K-30 and the tablet coatings:

TRAMAZAC SR 100: Opadry White 03F58750 (containing hypromellose, titanium dioxide, polyethylene glycol and talc).

TRAMAZAC SR 150: Opadry Orange 03F53885 (containing hypromellose, titanium dioxide, polyethylene glycol, talc, iron oxide yellow and iron oxide red).

TRAMAZAC SR 200: Opadry Pink 03F84640 (containing hypromellose, titanium dioxide, polyethylene glycol, talc, iron oxide red, iron oxide yellow and quinoline yellow).

What TRAMAZAC SR looks like and contents of the pack

TRAMAZAC SR 100: White to off-white, round shaped, biconvex, film-coated tablets, debossed with “100” on one side and plain on the other side.

TRAMAZAC SR 150: Pale orange, round shaped, biconvex, film-coated tablets, debossed with “150” on one side and plain on the other side.

TRAMAZAC SR 200: Slightly brownish orange, round shaped, biconvex, film-coated tablets, debossed with “200” on one side and plain on the other side.

White opaque PVC/PVDC/aluminium blister strips containing 10 tablets per blister strip. 10, 30, 60 or 100 tablets will be packed into a cardboard box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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