PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

Tradolacet 100 SR, 100 mg Sustained-release Tablets

Tradolacet 200 SR, 200 mg Sustained-release Tablets

Tramadol hydrochloride

Contains sugar (lactose monohydrate 36 mg per 100 mg tablet

and 20 mg per 200 mg tablet)

Read all of this leaflet carefully before you start taking Tradolacet SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Tradolacet 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 Tradolacet SR is and what it is used for
2. What you need to know before you take Tradolacet SR
3. How to take Tradolacet SR
4. Possible side effects
5. How to store Tradolacet SR
6. Contents of the pack and other information

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

Tradolacet SR is a painkiller belonging to the class of medicines called opioids that act on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

Tradolacet SR is used for the treatment of moderate to severe pain.

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

Do not take Tradolacet SR:

- if you are hypersensitive (allergic) to tramadol hydrochloride or opioids, or any of the other ingredients of Tradolacet SR, listed in section 6;
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tradolacet SR (see "Other medicines and Tradolacet SR");
- if you are an epileptic;
- as a substitute in drug withdrawal;
- if you have difficulty breathing or if you have poor circulation or inadequate oxygenation of the blood;
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- if you are pregnant or breastfeeding your baby;
- if you are younger than 12 years of age;
- If you are younger than 18 years of age following tonsillectomy and/or adenoidectomy.

Warnings and precautions

Take special care with Tradolacet SR:

Tell your doctor:

- if you think that you are addicted to other pain relievers (opioids)
- if you suffer from consciousness disorders (if you feel that you are going to faint)
- if you are in a state of shock (cold sweat may be a sign of this)
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease)
- if you have difficulty in breathing
- if you have a tendency towards epilepsy or fits because the risk of a fit may increase, especially if you are taking a higher dose of Tradolacet SR
- if you suffer from a liver or kidney disease
- if you have any sleep-related breathing problems, e.g., sleep apnoea, where breathing repeatedly stops and starts. Tradolacet SR may increase the risk of these breathing problems.

Please note that Tradolacet SR may lead to physical and psychological addiction. When Tradolacet SR is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with Tradolacet SR should only be carried out for short periods and under strict medical supervision.

Please also inform your doctor if one of these problems occurs during Tradolacet SR treatment or if they applied to you in the past.

Tramadol as in Tradolacet SR is transformed in the 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 are more likely to get serious side effects. If you notice any of the following side

effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Hyponatraemia (when the concentration of sodium in your blood is abnormally low) can occur in some patients e.g., the elderly or if you are also taking other medicines that may cause hyponatraemia. Please inform your doctor if you experience symptoms such as decreased ability to think, headaches, nausea, poor balance, confusion, seizures, coma.

Children and adolescents

On account of the dosage strength, Tradolacet SR is not recommended for children below the age of 12 years.

Tradolacet SR should not be used in children who have reduced lung function due to other conditions.

Other medicines and Tradolacet SR

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

If you are taking any of the following medicines, please inform your doctor before taking Tradolacet SR:

- MAO inhibitors (certain medicines for the treatment of depression), it should not be taken together with Tradolacet SR

The pain-relieving effect of Tradolacet SR may be reduced and the length of time it acts may be shortened, if you take medicines which contain:

- carbamazepine (for epileptic fits)
- ondansetron (prevents nausea)

The risk of side effects increases,

- if you are taking tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tradolacet SR. You may feel drowsier, have difficulty breathing or feel that you might faint. If this happens tell your doctor.
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tradolacet SR at the same time. Your doctor will tell you whether Tradolacet SR is suitable for you.
- if you are taking certain antidepressants Tradolacet SR may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 ˚C.
- if you are taking anticoagulants (medicines for blood thinning), e.g., warfarin, together with Tradolacet SR. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Tradolacet SR with food and alcohol

Do not drink alcohol during treatment with Tradolacet SR as its effect may be intensified.

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 healthcare provider for advice before taking this medicine.

Pregnancy

Do not take Tradolacet SR if you are pregnant.

Breastfeeding

Do not breastfeed your baby while on treatment with Tradolacet SR.

Fertility

No effect on fertility have been observed in animal studies or post-marketing surveillance of Tradolacet SR.

Contraception

You should ensure that you always use effective contraception while you are taking Tradolacet SR. Your healthcare professional can advise you on which contraceptives to take.

Driving and using machines

Tradolacet SR may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery.

It is not always possible to predict to what extent Tradolacet SR may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which Tradolacet SR affects you.

Tradolacet SR contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Tradolacet SR.

3. How to take Tradolacet SR

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

Always take Tradolacet SR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and adolescents from the age of 12 years

The usual dose is one Tradolacet 100 SR sustained-release tablet twice daily (equivalent to 200 mg tramadol hydrochloride per day), preferably in the morning and evening. Take the doses at least 8 hours apart, unless your doctor has advised otherwise.

If pain is not relieved, your doctor may increase your dose to 150 mg or 200 mg sustained-release tablet twice daily, preferably in the morning and evening.

Do not exceed a total daily use of 400 mg Tradolacet SR.

How and when should you take Tradolacet SR?

Swallow the tablet whole with some liquid with or without meals. Do not break or chew the tablet.

Your doctor will tell you how long your treatment with Tradolacet SR will last. Do not stop treatment early because you feel better. If you have the impression that the effect of Tradolacet SR is too strong or too weak, tell your doctor or pharmacist.

Children

Tradolacet SR should not be used in children below the age of 12 years.

Elderly patients

Your doctor may recommend increasing the time between doses.

Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take Tradolacet SR. If in your case the insufficiency is mild or moderate, your doctor may recommend increasing the time between doses.

If you take more Tradolacet SR than you should

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 a dose of Tradolacet SR

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Tradolacet SR

If you interrupt or finish treatment with Tradolacet SR too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, you should discuss it with your doctor.

You should not suddenly stop taking Tradolacet SR unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

It is advisable to slowly reduce your dosage when you want to stop taking Tradolacet SR. People who have been taking Tradolacet SR tablets for some time may feel unwell if they abruptly stop taking them. They may experience the following:

- Feeling agitated, anxious, nervous or shaky.
- They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders.

- Panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus).
- Confusion, delusions, change of perception of the own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely.

If you experience any of these complaints after stopping Tradolacet SR, please consult your doctor.

4. Possible side effects

Tradolacet SR can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Tradolacet 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:

- slow breathing, shortness of breath (dyspnoea)

- difficulty breathing and bronchospasm
- irregular heartbeat, pounding of the heart, fast heartbeat, slow heartbeat
- seizures
- severe abdominal pain, nausea and vomiting, low blood pressure, extreme fatigue, decreased appetite, and weight loss (may indicate adrenal your adrenal glands are not functioning properly)
- twitching muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, muscle rigidity (these may be signs of a condition called serotonin syndrome)

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:

- dizziness
- difficulty in sleeping
- headache
- nausea
- constipation, dry mouth, vomiting
- excessive sweating
- tiredness

Less frequent side effects:

- changes in appetite
- hallucination, confusion, sleep disorders, delirium, anxiety and nightmares
- changes in mood (high spirits or irritable)
- increased or decreased activity
- difficulty making decisions

- abnormal sensations (e.g., itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupils (miosis)
- low blood pressure that happens when you stand up from sitting or lying down
- feeling faint or collapse, increase in blood pressure
- urge to be sick, stomach trouble, diarrhoea
- hives, blistering and peeling of skin
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria)

Side effects with unknown frequency

- decreased blood sugar level
- hiccups
- worsening of asthma
- low sodium levels (you may experience nausea, vomiting, headache, confusion, loss of energy, drowsiness and fatigue
- cramping, fatigue, muscle weakness, headache (may indicate a condition in which high levels of a hormone cause the body to retain water)

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. This includes any possible side effects not listed in this leaflet. 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 this medicine.

5. How to store Tradolacet SR

Store all medicines out of reach of children.

Store at or below 25 °C. Store in a cool dry place. Store in the original blister strip until required for use.

Do not use after the expiry date printed on the label/ carton.

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 Tradolacet SR contains

The active substance is tramadol hydrochloride.

The other ingredients are colloidal anhydrous silica, hypromellose, isopropyl alcohol, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Tablet coating:

Tradolacet 100 SR: Hypromellose, macrogol 6 000, talc, titanium dioxide E171.

Tradolacet 200 SR: Colour Quinoline Yellow E104, ferric oxide red E172, hypromellose, macrogol 6 000, talc and titanium dioxide E171.

What Tradolacet SR looks like and contents of the pack

Tradolacet 100 SR tablets are white to off white round, biconvex film-coated tablets with “100” embossed on one side and plain on other side.

Tradolacet 200 SR tablets are light orange to light pink, round, biconvex film-coated tablets with “200” embossed on one side and plain on other side.

Tradolacet SR 100 mg and 200 mg tablets are packed in white opaque PVC (250 µ) / Aluminium (0,025 mm) blisters of 10 tablets. The blisters are then packaged in an outer carton containing 30 or 60 tablets.

Holder of Certificate of Registration

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