PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 5

TRAMAL® SR 50/100/150 mg (tablet): tramadol hydrochloride.

Tramadol Hydrochloride

Contains Lactose.

Read all of this leaflet carefully before you start using TRAMAL SR tablets

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

1. What TRAMAL SR tablet is and what it is used for:

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

2. What you need to know before you take TRAMAL capsules

Do not take TRAMAL SR:

- If you are younger than 12 years of age;
- If you are younger than 18 years of age following tonsillectomy and/or adenoidectomy;
- if you are allergic to tramadol or any of the other ingredients of TRAMAL SR. (Refer to WHAT TRAMAL SR CONTAINS, above.);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with TRAMAL SR;
- If you have epilepsy;
- As a substitute in drug withdrawal.
- 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 are pregnant or breastfeeding your baby (see Pregnancy and Breastfeeding).

Warnings and special precautions:

Take special care with TRAMAL SR:

- if you think that you are addicted to other pain relievers (opioids);
- if you suffer from consciousness disorders (if you have fainting spells or you feel that you are going to faint);
- if you are in a state of shock (cold sweat may be a sign of it);
- if you have a tendency towards epilepsy or seizures because the risk of a seizure may increase; especially if the upper dose limit (400 mg) of TRAMAL SR is exceeded;
- if you suffer from a liver or kidney disease.
- if you suffer from lactose intolerance
- Tramadol works by being converted (metabolised) into its active component. If you convert (metabolise) Tramadol to this active component more rapidly and completely than other patients you are known as an ultra-rapid metaboliser. If you are an ultra rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking this medicine and consult with your doctor immediately.
- You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. 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 lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking TRAMAL, consult with your doctor immediately

TRAMAL SR can lead to psychological and physical dependence or addiction in some people, especially with long term use. The dose needed to achieve the desired effect may increase with time. TRAMAL SR should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid pain-killers. Please also inform your doctor if any of these problems occur during TRAMAL SR treatment or if they applied to you in the past.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Sleep-related breathing disorders.
TRAMAL SR contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep related hypoxemia (low level of oxygen in the blood). The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

Other medicines and TRAMAL SR:
Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

TRAMAL SR should not be used together with Monoamine oxidase (MAO) inhibitors (certain medicines for the treatment of depression), or within 2 weeks of stopping treatment with this.

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

- Carbamazepine (for epileptic seizures);
- Ondansetron (prevents nausea).

Your doctor will tell you whether you should have TRAMAL SR, and at what dose.

The risk of side effects increases,

- If you are taking tranquilisers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while having TRAMAL SR. You may feel drowsier or feel that you might faint. If this happens tell your nurse or doctor.
- If you are taking medicines which may cause seizures such as certain antidepressants or antipsychotics. The risk of having a seizure may increase if you take TRAMAL SR at the same time. Your doctor will tell you whether TRAMAL SR tablets are suitable for you.
- If you are taking certain antidepressants such as Selective Serotonin Reuptake Inhibitors or MAO inhibitors. TRAMAL SR may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including 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 warfarin (medicine for blood thinning) together with TRAMAL SR. The effect of warfarin on blood clotting may be increased and bleeding may occur.

TRAMAL SR with food, drink and alcohol:

Do not drink alcohol during treatment with TRAMAL SR as the effects of TRAMAL SR and alcohol may intensify each other. Food does not influence the effect of TRAMAL SR.

Pregnancy, Breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking TRAMAL SR.

If TRAMAL SR is used on a long term basis during pregnancy, it will lead to harm (withdrawal symptoms) in newborns.

You should not take TRAMAL SR if you are pregnant.

The use of TRAMAL SR is not recommended during breastfeeding. TRAMAL SR is excreted into breast milk. If you are taking TRAMAL SR you should not breastfeed your baby.

Driving and using machines:

TRAMAL SR may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. Do not drive a car or other vehicle, do not use electric tools or operate machinery until you are sure how TRAMAL SR affects you.

Important information about some of the ingredients of TRAMAL SR:

TRAMAL SR contains lactose. If you suffer from one of the rare hereditary diseases such as galactose or lactose intolerance, or glucose/galactose malabsorption, please ask your doctor for advice.

3. How to take TRAMAL SR:

Do not share medicines prescribed for you with any other person. Always take TRAMAL SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. The lowest pain-relieving dose should be taken orally. Do not take more than 400 mg tramadol hydrochloride daily.

Always swallow TRAMAL SR prolonged-release tablets whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take tablets on an empty stomach or with meals.

Adults and children over 12 years:

Take 100 mg twice daily, with a little liquid, independent of meals, preferably in the morning and evening. 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. You should not take TRAMAL SR for longer than is absolutely necessary.

Elderly patients (above 75 years):

A dose reduction and/or prolongation of the interval between doses are recommended.

Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take TRAMAL SR.

How long should you take TRAMAL SR

You should not take TRAMAL SR for longer than recommended by your doctor. If you need to be treated for a longer period, your doctor will check at regular short intervals (if necessary with breaks in treatment) whether you should continue to take TRAMAL SR and at what dose.

If you have the impression that the effect of TRAMAL SR is too strong or too weak, talk to your doctor or pharmacist.

If you take more TRAMAL SR than you should:

If you have taken an additional dose by mistake, contact your doctor or go to the nearest hospital. You should have your next dose as your doctor prescribed it for you.

After taking very high doses, pin-point or wide pupils, vomiting, fall in blood pressure, fast heart beat, feeling faint, reduced level of consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to stoppage of breathing may occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take TRAMAL SR:

If you forget to take the tablets, your pain may return. Do not take a double dose to make up for forgotten individual doses simply continue taking the tablets as before.

If you stop taking TRAMAL SR:

If you interrupt or finish treatment with TRAMAL SR too soon, your pain may return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

If you have been taking TRAMAL SR prolonged release tablets for some time you may feel unwell if you abruptly stop taking them, You may feel agitated, anxious, nervous or shaky. You may be hyperactive, have difficulty in sleeping and have stomach or bowel disorders. You may get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in ears (tinnitus). Further unusual Central Nervous System (CNS) symptoms, i.e. confusion, delusions, change in how you see (perceive) your own personality (depersonalisation), and change in how you see (perceive) reality (derealisation) and delusion of persecution (paranoia) have been reported. If you experience any of these complaints after you stop taking TRAMAL SR, consult your doctor.

4. Possible side effects:

TRAMAL SR can have side effects.

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

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

- swollen face, tongue and/or throat, and/or difficulty swallowing or breathing or wheezing;
- rash, swelling or itching of skin;
- shock (sudden circulation failure).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRAMAL 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 or experience any of the following:

- changes in the way your heart beats, for example, if you notice that your heart is beating faster;
- pounding (this may particularly occur when you are under strain, have a slow heartbeat, an increase in blood pressure or change position from an upright position to sitting or laying down;
- feeling faint;
- loss of consciousness;
- slow breathing;
- shortness of breath;
- seizures (fits);
- passing urine with difficulty or pain, passing less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- dizziness;
- headaches;

- drowsiness;
- abnormal sensations for example if you experience itching, tingling, or numbness;
- trembling;
- muscle twitches;
- uncoordinated movement;
- speech disorder;
- changes in appetite;
- hallucination;
- confusional state;
- sleep disorders;
- delirium;
- anxiety;
- nightmares;
- changes in mood for example you may feel happy or irritated;
- decreased activity;
- restlessness;
- changes in the way you see or view things;
- blurred vision;
- excessive widening of your pupils;
- narrowing of the pupil;
- nausea (feeling sick urge to vomit);
- vomiting;
- constipation;
- dry mouth;
- stomach trouble (e.g. feeling of pressure in the stomach, bloating);

- diarrhoea (frequent or loose watery stools);
- sweating more than is normal for you;
- weak muscles;
- liver enzyme increased;
- fatigue.
- Low levels of sodium in the blood and/or inappropriate antidiuretic hormone secretion (SIADH)

If any of the side effects get serious, or if you experience one of the above –mentioned serious side effects, call the nearest doctor immediately. If you experience any side effects not listed 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 "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 TRAMAL SR.

Alternatively, you may report side effects experienced with TRAMAL SR directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5. How to store TRAMAL SR:

- Store all medicines out of reach of children.
- Store TRAMAL SR in a cool, dry place, at or below 25 °C

- TRAMAL SR can be kept for only a limited period.
- Do not use TRAMAL SR after the date (month and year) mentioned after “EXP”, even if it has been stored properly.
- Return 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 TRAMAL SR contains:

- The active ingredient is tramadol hydrochloride.
- The other ingredients are: microcrystalline cellulose, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, propylene glycol, colloidal anhydrous silica, talc, titanium dioxide. (See section : TRAMAL SR contains lactose)

TRAMAL SR 50/150 mg tablets also contain quinoline yellow and iron oxides.

What TRAMAL SR looks like and contents of the pack

TRAMAL SR 50 mg: Pale yellow, round, biconvex, film-coated tablet. Engraved T0/Grünenthal logo.

TRAMAL SR 100 mg: White, round, biconvex, film-coated tablet. Engraved T1/Grünenthal logo.

TRAMAL SR 150 mg: Pale-orange, round, biconvex, film-coated tablet. Engraved T2/Grünenthal logo

Folding carton box containing 10, 30, 60 or 100 tablets, in blister strips of 10’s.

The blister strips are white & opaque PVC/PVDC - aluminium blister foil packs or white & opaque PP- Aluminium blister foil packs**.**

Holder of certificate of registration:

JANSSEN PHARMACEUTICA (Pty.) Ltd.

(Reg No.: 1980/011122/07)

2 Medical Road,

Halfway House, Midrand, 1685

Tel: +27 (11) 518 7000

MedInfoZA@its.jnj.com

This leaflet was revised in:

15 July 2021

Registration number:

Tramal SR 50 mg: 42/2.9/0283

Tramal SR 100 and 150 mg: 31/2.9/0646/7

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.