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

Read all of this leaflet carefully before you start taking 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 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.

1. WHAT TRAMAL SR CONTAINS
- The active ingredient is tramadol hydrochloride.
- The other ingredients are: microcrystalline cellulose, hypromellose, lactose monohydrate, macrogol 6 000, magnesium stearate, propylene glycol, colloidal anhydrous silica, talc, titanium dioxide.

2. WHAT TRAMAL SR 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.

3. BEFORE YOU TAKE TRAMAL SR
Do not take TRAMAL SR:
- 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 and your seizures are not adequately controlled by treatment;
- 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 suffer from lactose intolerance.

In such cases, please consult your doctor before taking TRAMAL SR.

Epileptic seizures have been reported in patients taking TRAMAL SR at the recommended dose level. The risk is increased when doses of TRAMAL SR exceed the recommended daily dose limit (400 mg).

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

Please also inform your doctor if any of these problems occur during TRAMAL SR treatment or if they applied to you in the past.

Taking TRAMAL SR with food and drink:
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 and Breastfeeding:
Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machinery:
TRAMAL 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, and do not work without a firm hold.
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) elderly 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 had an additional dose by mistake, contact your doctor or go to the nearest hospital. You should have your next dose as prescribed. After taking very high doses, pin-point or wide pupils, vomiting, or go to the nearest hospital. You should have your next dose as prescribed.

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, pain is likely to 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, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor. People who have been taking TRAMAL SR prolonged release tablets for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty in sleeping and have stomach or bowel disorders. They 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, changes of perception of the own personality (depersonalisation), and change in perception of 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.

5. POSSIBLE 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.

Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred.

You should see a doctor immediately if you experience symptoms such as swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing. TRAMAL SR can have side effects. The most frequent side effects during treatment with TRAMAL SR tablets are nausea and dizziness.

Immune system disorders
Less frequent: Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred.

Heart and blood circulation disorders
Less frequent: Effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain. Slow heartbeat. Increase in blood pressure.

Nervous system disorders
Frequent: Dizziness, headache, drowsiness.

Less frequent: Abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, loss of consciousness, speech disorders. Epileptic fits have occurred.

Metabolism and nutrition disorders
Less frequent: Changes in appetite.

Psychiatric disorders
Less frequent: Hallucination, confusion, state, sleep disorders, delirium, anxiety and nightmares.

Psychological complaints may appear after treatment with Tramal SR. These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and changes in mental perception, which may lead to errors in judgment. Dependence may occur.

Eye disorders
Less frequent: Vision blurred, constriction of the pupil, excessive dilation of the pupils.

Respiratory disorders
Less frequent: Slow breathing, shortness of breath.

Stomach and bowel disorders
Frequent: Nausea, constipation, dry mouth, vomiting
Less frequent: urge to vomit (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

Skin disorders
Frequent: Sweating.
Less frequent: Skin reactions (e.g. itching, rash).

Muscle disorders
Less frequent: Weak muscles.

Liver and biliary disorders
Less frequent: Liver enzyme increased.

Urinary disorders
Less frequent: Passing urine with difficulty or pain, passing less urine than normal.

General disorders
Frequent: Fatigue.
If you experience one of the above mentioned serious side-effects, call the nearest doctor immediately. If you experience side-effects not listed in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF TRAMAL SR
Store TRAMAL SR in a cool, dry place, at or below 25 °C. Store all medicines “OUT OF THE REACH OF CHILDREN”. 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 sewage systems (e.g. toilets).

7. PRESENTATION OF TRAMAL SR
The blister strips are white & opaque PVC/PVDC - aluminium blister foil packs with the respective patient information leaflet. Engraved T1/Grünenthal logo.

8. IDENTIFICATION OF TRAMAL SR
TRAMAL SR 100 mg: White, round, biconvex, film-coated tablet.

9. REGISTRATION NUMBER
Tramal SR 100: 10767

10. NAME AND ADDRESS OF REGISTRATION HOLDER
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11. DATE OF PUBLICATION
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