LF-103323-01
Package Leaflet: Information for the User

Tramulief® SR

100 mg, 150 mg and 200 mg

Prolonged-release tablets

(Tramadol Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT TRAMULIEF SR IS AND WHAT IT IS USED FOR

Tramadol, the active substance in Tramulief SR, is a pain killer belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the brain and spinal cord.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRAMULIEF SR

Do not take Tramulief SR:
- if you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (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 monoamine oxidase inhibitors (MAOIs) (certain medicines used for the treatment of depression) or have taken them in the last 14 days before treatment with Tramulief SR (see "Other medicines and Tramulief SR");
- if you are an epileptic and your fits are not adequately controlled by treatment;
- as a substitute in drug withdrawal.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tramulief SR if:
- you think that you are addicted to other pain relievers (opioids);
- you suffer from consciousness disorders (if you feel that you are going to faint);
- you are in a state of shock (cold sweat may be a sign of this);
- you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- you suffer from liver or kidney disease;
- you have difficulty in breathing;
- you have a tendency towards epilepsy or fits, because the risk of a fit may increase. Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Please note that Tramulief SR may lead to physical and psychological addiction. When Tramulief 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 Tramulief 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 Tramulief SR treatment or if they applied in the past.

Other medicines and Tramulief SR

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines.
Tramulief SR should not be taken together with monoamine oxidase inhibitors (MAOIs) (certain medicines for the treatment of depression).

The pain-relieving effect of Tramulief SR may be reduced and the length of time it acts may be shortened, if you also take medicines containing:
- carbamazepine (for epileptic fits);
- buprenorphine, nalbuphine, or pentazocine (pain relievers);
- ondansetron (prevents nausea).

Your doctor will tell you whether you should take Tramulief SR and at what dose.
The risk of side effects increases:
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tramulief SR at the same time. Your doctor will tell you whether Tramulief SR is suitable for you;
- if you are taking certain antidepressants. Tramulief 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 take coumarin anticoagulants (medicines for blood thinning), such as warfarin, together with Tramulief SR. These medicines may have an effect on blood clotting and bleeding may occur;
- if you take tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramulief SR. You might feel drowsier or feel that you might faint. If this happens tell your doctor.

Tramulief SR with food and alcohol

Do not drink alcohol during treatment with Tramulief SR as its effect may be intensified. Food does not influence the effect of Tramulief SR.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramulief SR if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns. Generally, the use of Tramulief SR is not recommended during breast-feeding. Small amounts of Tramulief SR are excreted into breast milk. With a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

Driving and using machines

Tramulief SR can 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 any other vehicle, do not use electric tools or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- do not drive while taking this medicine until you know how it affects you;
- it is an offence to drive if this medicine affects your ability to drive;
- however, you would not be committing an offence if:
  - the medicine has been prescribed to treat a medical or dental problem and;
  - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and;
  - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. HOW TO TAKE TRAMULIEF SR

Always use this medicine 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. In general the lowest pain-relieving dose should be taken.

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

Adults and adolescents from the age of 12 years:
One Tramulief SR 100 mg tablet twice daily (equivalent to 200 mg tramadol hydrochloride per day), preferably in the morning and evening.
One Tramulief SR 150 mg tablet twice daily (equivalent to 300 mg tramadol hydrochloride per day), preferably in the morning and evening.
One Tramulief SR 200 mg tablet twice daily (equivalent to 400 mg tramadol hydrochloride per day), preferably in the morning and evening.
Your doctor may prescribe a different, more appropriate dosage strength of Tramulief SR if necessary.
Do not take more than 400 mg tramadol hydrochloride daily, unless your doctor has instructed you to do so.

Use in children
Tramulief SR is not suitable for children below the age of 12 years.

Elderly patients
In elderly patients (above 75 years) the excretion of tramadol may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.

Severe liver or kidney disease (insufficiency)/dialysis patients
Patients with severe liver and/or kidney insufficiency should not take Tramulief SR. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramulief SR?
Tramulief SR tablets are for oral use.
Always swallow Tramulief SR tablets whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the tablets on an empty stomach or with meals.

How long should you take Tramulief SR for?
You should not take Tramulief SR for longer than necessary. 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 Tramulief SR tablets and at what dose.
If you have the impression that the effect of Tramulief SR is too strong or too weak, talk to your doctor or pharmacist.

If you take more Tramulief SR than you should
If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.
After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heart beat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing may occur. In such cases a doctor should be called immediately.

If you forget to take Tramulief 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 tablets as before.

If you stop taking Tramulief SR
If you interrupt or finish treatment with Tramulief SR too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.
Generally there will be no after-effects when treatment with Tramulief SR is stopped. However, on rare occasions, people who have been taking Tramulief SR tablets for some time may feel unwell if they stop taking them abruptly. They may feel agitated, anxious, nervous or shaky. They may be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Rarely, people may get panic attacks, hallucinations, delusions, paranoia or feel a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and "ringing" in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of one's own personality (depersonalization), 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 Tramulief SR, please consult your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Usually the frequency of side effects is classified as follows:
- very common (may affect more than 1 in 10 people);
- common (may affect up to 1 in 10 people);
- uncommon (may affect up to 1 in 100 people);
- rare (may affect up to 1 in 1,000 people);
- very rare (may affect up to 1 user in 10,000);
- not known (frequency cannot be estimated from the available data).

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

The most common side effects during treatment with Tramulief SR are nausea and dizziness, which occur in more than 1 out of 10 patients.

Heart and blood circulation disorders
Uncommon: effects on the heart and blood circulation (pounding of the heart, fast heart beat, feeling faint or collapse). These adverse effects may occur particularly when patients are in an upright position or under physical strain.
Rare: slow heart beat, increase in blood pressure.

Metabolism and nutrition disorders
not known: decrease in blood sugar level

Nervous system disorders
Very common: dizziness.
Common: headaches, drowsiness.
Rare: changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope).
If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.
Not known: Speech disorders.

Psychiatric disorders
Rare: delirium (a state of mental confusion), hallucinations, confusion, sleep disorders, anxiety and nightmares.
Psychological complaints may appear after treatment with Tramulief SR. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (slowing down but sometimes an increase in activity) and being less aware and less able to make decisions, which may lead to errors in judgment.
Dependence may occur.

Eye disorders
Rare: miosis (excessive constriction of the pupil of the eye), blurred vision.
Not known: extreme pupil dilation (mydriasis).

Respiratory disorders
Rare: shortness of breath (dyspnoea).
Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

Stomach and bowel disorders
Very common: feeling sick.
Common: being sick, constipation, dry mouth.
Uncommon: urge to vomit (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

Skin disorders
Common: sweating.
Uncommon: skin reactions (e.g. itching, rash).

Muscle disorders
Rare: weak muscles.

Liver and biliary disorders
Very rare: increase in liver enzyme values.

Urinary disorders
Rare: passing urine with difficulty or pain, passing less urine than normal.

General disorders
Common: fatigue.
Rare: allergic reactions (e.g. difficulty breathing, wheezing, swelling of the skin) and shock (sudden circulatory failure) occur in very rare cases.

If Tramulief SR tablets are taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly signs of withdrawal may appear (see "If you stop taking Tramulief SR").

Reporting of side effects
If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRAMULIEF SR
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister and / or bottle and the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Tramulief SR contains
The active substance is tramadol hydrochloride.
– 1 tablet of Tramulief SR 100 mg contains 100 mg tramadol hydrochloride.
– 1 tablet of Tramulief SR 150 mg contains 150 mg tramadol hydrochloride.
– 1 tablet of Tramulief SR 200 mg contains 200 mg tramadol hydrochloride.

The other ingredients are: calcium hydrogen phosphate (E341), hydroxypropyl cellulose (E463), colloidal anhydrous silica (E551), and magnesium stearate (E470b).

What Tramulief SR looks like and contents of the pack
Tramulief SR 100 mg tablets are off white, round biconvex tablets.
Tramulief SR 150 mg tablets are off white, capsule-shaped tablets.
Tramulief SR 200 mg tablets are off white, capsule-shaped tablets.

Tramulief SR 100 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

Tramulief SR 150 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

Tramulief SR 200 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 white tablets in blisters or in plastic tablet containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer
MA Holder: Amdipharm UK Limited, Capital House,
85 King William Street, London EC4N 7BL, UK
Manufacturers: Farmaceutisch Analytisch Laboratorium Duiven BV, Dijkgraaf 30, Duiven, The Netherlands
Medochemie Ltd., Facility A-Z, Mich. Erakleous, Ayios Athanassios Industrial Area, Limassol, Cyprus.

This medicinal product is authorized in the Member States of the EEA under the following names:

The Netherlands:
Tramadol HCl Retard 100 mg
Tramadol HCl Retard 150 mg
Tramadol HCl Retard 200 mg

Cyprus, Lithuania and Malta:
Mabron Retard 100 mg
Mabron Retard 150 mg
Mabron Retard 200 mg

Ireland:
Tramapine 100 mg SR tablets
Tramapine 150 mg SR tablets
Tramapine 200 mg SR tablets

Sweden:
Tramadol SR Medartuum 100 mg
Tramadol SR Medartuum 150 mg
Tramadol SR Medartuum 200 mg

United Kingdom:
Tramulief SR 100 mg
Tramulief SR 150 mg
Tramulief SR 200 mg

This leaflet was last revised in September 2017.

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