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 a 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;
- you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Tramadol SR may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.
- you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramulief SR').

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 'Possible side effects').

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramulief SR:

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

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).

Tramadol 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.

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

Sleep-related breathing disorders

Tramulief SR can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level 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. A dose reduction may be considered by your doctor.

Children and adolescents

Use in children with breathing problems

Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

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).
Concomitant use of Tramadol SR and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Tramadol SR together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
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 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 serotonin syndrome (see section 4 'Possible side effects').
- 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 tranquillizers, 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 and breast-feeding

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.

Pregnancy

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.

Breast-feeding

Tramadol is excreted into breast milk. For this reason, you should not take tramadol more than once during breast-feeding, or alternatively, if you take Tramadol SR more than once, you should stop breast-feeding.

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

You should not suddenly stop taking this medicine 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).

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 people);
- 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.

Other side effects include:

Very common (may affect more than 1 in 10 people):

- dizziness
- nausea
- feeling sick.

Common (may affect up to 1 in 10 people):

- headaches
- drowsiness
- constipation
- dry mouth
- being sick
- sweating
- fatigue
- low energy (weakness).

Uncommon (may affect up to 1 in 100 people):

- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse)
- urge to vomit (retching)
- stomach trouble (e.g. feeling of pressure in the stomach, bloating)
- diarrhoea
- skin reactions (e.g. itching, rash).

Rare (may affect up to 1 in 1,000 people):

- slow heartbeat
- increase in blood pressure
- changes in appetite
- abnormal sensations (e.g. itching, tingling, numbness)
- trembling, slow breathing
- epileptic fits
- muscle twitches
- uncoordinated movement
- transient loss of consciousness (syncope)
- hallucinations
- confusion
- anxiety and nightmares
- psychological complaints
- change in mood (mostly high spirits, occasionally irritated mood)
- changes in activity (usually suppression, occasionally increase)
- dependence
- miosis (excessive constriction of the pupil of the eye)
- blurred vision
- shortness of breath (dyspnoea)
- weak muscles
- passing urine with difficulty or pain
- passing less urine than normal
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin)
- shock (sudden circulation failure).

Very rare (may affect up to 1 user in 10,000 people)

- increase in liver enzyme values
- shock (sudden circulation failure).

Not known (frequency cannot be estimated based on available data):

- decrease in blood sugar level
- speech disorders
- excessive dilation of the pupils (mydriasis).
- hiccups
- serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take Tramulief SR').

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 yellow card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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, Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, United Kingdom
Manufacturers:
Farmaceutisch Analytisch Laboratorium Duiven B.V,
Dijkgraaf 30, Duiven, The Netherlands
Medochemie Ltd., Facility A-Z, Mich. Erakleois, 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 100mg

Mabron Retard 150mg

Mabron Retard 200mg

Ireland:

Tramapine 100mg SR tablets

Tramapine 150mg SR tablets

Tramapine 200mg SR tablets

Sweden:

Tramadol SR Medartuum 100mg

Tramadol SR Medartuum 150mg

Tramadol SR Medartuum 200mg

United Kingdom:

Tramulief SR 100mg

Tramulief SR 150mg

Tramulief SR 200mg

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