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Package leaflet: Information for the user

MAXITRAM SR 50 mg, 100 mg, 150 mg and 200 mg prolonged-release capsule, hard

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Tramadol hydrochloride – the active substance of MAXITRAM SR –belongs to a group of medicines known as opioid analgesics or painkillers. Its pain-relieving action is due to its effect on specific nerve cells in the spinal cord and brain.
MAXITRAM SR is used in the treatment of moderate to severe pain.

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

Do not take MAXITRAM SR:
- if you are allergic to tramadol or any of the other ingredients of this medicine (listed in section 6).
- if you are intoxicated with alcohol or with sedative drugs including sleeping pills, other pain-killers or psychotropic medicines (medicines that affect mood and emotions)
- if you are taking, or have taken in the last two weeks, certain medicines called “monoamine oxidase inhibitors” or MAOIs (used to treat depression). The combination could result in a serious, potentially life threatening interaction (see “Other medicines and MAXITRAM SR)
- if you have epilepsy that is not controlled with your current medicine

MAXITRAM SR is not suitable as a drug substitute for the treatment of drug addiction.
MAXITRAM SR is not suitable for use in children under 25 kg body weight.
MAXITRAM SR is contraindicated in children below 12 years of age.

Warnings and Precautions
Talk to your doctor, pharmacist or nurse before taking MAXITRAM SR:
- 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 epilepsy or seizures (fits) or have had them in the past, because tramadol could increase the risk of you having further fits.
- if you have liver or kidney problems.
- if you experience 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;

Sleep-related breathing disorders
Tramadol 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.

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.

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).

As with all opioids, tramadol should be used with caution, and only under medical supervision in seriously ill patients including those with impaired breathing, excessively low blood pressure (shock), serious head injury or brain diseases that may cause elevated pressure in the skull.

As with all opioids, tramadol may 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. Tramadol should be used with caution, and only for short periods, in patients who are addicted to other opioid pain-killers.

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 MAXITRAM SR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
The pain-relieving effect of MAXITRAM SR may be weakened and/or shortened if you also take medicines containing:
- carbamazepine (used to treat epilepsy)
- pentazocine, nalbuphine or buprenorphine (pain killers)
- ondansetron (used to stop you feeling sick).

Your doctor will tell you whether you should take MAXITRAM SR, and which 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 MAXITRAM SR at the same time. Your doctor will tell you whether MAXITRAM SR is suitable for you.
- if you are taking certain antidepressants. MAXITRAM 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 MAXITRAM SR at the same time as sedative medicines such as tranquillizers, or sleeping pills and other pain relievers (morphine, codeine– also as cough medicine). You may feel excessively drowsy or feel that you might faint. If it happens tell your doctor.
- if you take MAXITRAM SR at the same time as alcohol. Tramadol may increase the intoxicating effect of alcohol and therefore you should be cautious if you wish to drink alcohol during treatment with MAXITRAM SR.
- if you take MAXITRAM SR at the same time as medicines that inhibit blood clotting, such as warfarin. The dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.

Do not take MAXITRAM SR at the same time as medicines called “monoamine oxidase inhibitors” (which are used to treat depression), or if you have taken one in the past 2 weeks.

Concomitant use of MAXITRAM 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 MAXITRAM 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.

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

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

MAXITRAM SR may affect an unborn child. Therefore, it should not be taken during pregnancy.

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

Based on human experience tramadol is suggested not to influence female or male fertility.

Driving and using machines
MAXITRAM SR may cause side effects such as drowsiness and blurred vision. If this happens, do not drive or use any tools/machines and do not perform any hazardous tasks.

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.
MAXITRAM SR contains benzoates, sucrose and sodium benzoate
This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions, some of which may be delayed.
This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 0.0001 mg of sodium benzoate in each dosage unit.

MAXITRAM SR contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release capsule, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE MAXITRAM SR

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.
Always take MAXITRAM SR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The usual doses are given below. Your doctor may gradually increase or decrease your dose depending on how you respond to the treatment.

Adults and adolescents aged 12 and over:
50 mg capsules: The usual dose is two to four 50 mg capsules taken twice a day, equivalent to 200 to 400 mg per day.
100 mg capsules: The usual dose is one to two 100 mg capsules taken twice a day, equivalent to 200 to 400 mg per day.
150 mg capsules: The usual dose is one 150 mg capsule taken twice a day, equivalent to 300 mg per day.
200 mg capsules: The usual dose is one 200 mg capsule taken twice a day, equivalent to 400 mg per day.
The capsules should be taken in the morning and evening. You should not normally take more than 400 mg a day.

Use in children:
This medicinal product is not suitable for use in children below 25 kg body weight which in general does not allow for individualized dosage in children below 12 years of age. Other form(s) of this medicine may be more suitable for children; ask your doctor, pharmacist or nurse.

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 problems, should not take MAXITRAM SR.
If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Route and method of administration
For oral use.
The capsules should be swallowed whole with a glass of water.
The capsules can be taken with or without food. They should NOT be chewed, divided or crushed.

How long should you take MAXITRAM SR
You should not take MAXITRAM 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 MAXITRAM SR and at what dose.
If you have the impression that the effect of MAXITRAM SR is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAXITRAM SR than you should
If high doses are taken accidentally, you should contact your doctor immediately or go to your nearest hospital casualty department. A number of symptoms may occur. These might include: very small pupils, vomiting (being sick), a fall in blood pressure, a fast heartbeat, collapse, fainting or even coma, epileptic fits and difficulties in breathing or shallow breathing.

If you forget to take MAXITRAM SR, take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking MAXITRAM SR, your pain may return.
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).
If you have been taking this medicine for a very long time, you may get the following side effects if you suddenly stop treatment: restlessness, anxiety, nervousness, shaking or an upset stomach. Very few people may get panic attacks, hallucinations, 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 the own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you get any of these effects after stopping treatment with MAXITRAM SR, please talk to your doctor.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

MAXITRAM SR can occasionally cause allergic reactions although serious allergic reactions (including anaphylaxis and angioedema) are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).
The following side effects may occur:
Very common: may affect more than 1 in 10 people
- Feeling sick (nausea)
- Dizziness

Common: may affect up to 1 in 10 people
- Headache
- Being sick (vomiting)
- Constipation
- Fatigue (tiredness)
- Drowsiness
- Dry mouth
- Sweating (hyperhidrosis)

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). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- Urge to be sick (retching)
- Stomach trouble (e.g. feeling pressure in the stomach, bloating, diarrhoea)
- Skin reactions (e.g. itchiness, rash, sudden onset of skin redness)

Rare: may affect up to 1 in 1,000 people
- Slow heartbeat
- Increased in blood pressure
- Hallucinations, confusion, sleep disorders, delirium, anxiety and nightmares
- Changes in appetite
- Abnormal sensations (e.g. itching, tingling numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders
- Slow breathing, shortness of breath (dyspnoea)
- Blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis)
- 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.
- Weak muscles
- Passing less urine than normal (dysuria) or passing urine with difficulty or pain
- Drug dependence may occur.
- Psychological complaints may appear after treatment with MAXITRAM 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 decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
- Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- Allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.

Very rare: may affect up to 1 in 10,000 people
- Increased levels of liver enzymes

Not known: frequency cannot be estimated from the available data
- Decrease in blood sugar level (hypoglycaemia)
- Hiccups

When treatment is stopped abruptly, signs of withdrawal may appear (see "If you stop taking MAXITRAM SR").

Reporting of side effects
If you get any 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 directly via 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 MAXITRAM 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 the carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. 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 MAXITRAM SR contains
The active substance is tramadol hydrochloride. Each capsule contains 50 mg, 100 mg, 150 mg or 200 mg of tramadol hydrochloride equivalent to 43.91 mg, 87.82 mg, 131.73 mg or 175.64 mg tramadol.
The other ingredients are:
- Sugar spheres (maize starch and sucrose)
- Macrogol 4000
- Polyacrylate dispersion 30% (ethyl acrylate, methyl methacrylate, nonoxynol)
- Dimeticone emulsion (dimeticone, (t-octylphenoxy) polyethoxyethanol, Macrogol 600, polyethylene-sorbitan- monolaurate, sodium benzoate, propyl-4-hydroxybenzoate (E216), methyl-4-hydroxybenzoate (E218), propylene glycol, sorbic acid)
- Hypromellose
- Talc
- Gelatin
- Titanium dioxide (E 171)
- Yellow iron oxide (E172) [100 mg, 150 mg, 200 mg capsules only]

What MAXITRAM SR looks like and contents of the pack
All strengths of MAXITRAM SR capsules contain white spherical microgranules ("beads")
50 mg gelatin capsules are white opaque
100 mg gelatin capsules have an opaque yellow cap and natural transparent body
150 mg gelatin capsules are opaque yellow
200 mg gelatin capsules have an opaque yellow cap and opaque white body
Pack sizes: 10, 20, 28, 30, 50, 56, 60, 100 capsules. Hospital packs: 500 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Ethypharm, 194 Bureaux de la Colline, Bâtiment D, 92213 Saint-Cloud Cedex, FRANCE

Distributor
Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, United Kingdom

Manufacturer
MACARTHYS LABORATORIES LIMITED, TA MARTINDALE PHARMA, Bampton road, Harold hill, Romford, RM38UG, United Kingdom

For any information about this medicine, please contact 0161 488 5555.

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