

TRAMUNDIN™ Retard Tablets 100 mg

Active substance: tramadol hydrochloride



Composition

Pharmacologically active component

1 retard tablet contains 100 mg tramadol hydrochloride

Other components

Lactose monohydrate, cetylstearyl alcohol, ethylcellulose, dibutyl sebacate, oleic acid, colloidal silicon dioxide, magnesium stearate, methylhydroxypropylcellulose, macrogol 400, talc, colouring agent E 171.

Drug form and packing content

Retard tablets, 10, 30, 50

Central-acting analgesic of the opioid group

Mundipharma GmbH
Mundipharmastr. 2
65549 Limburg (Lahn), Germany

Indications

Moderately severe to severe pain

Contraindications

When must you not take TRAMUNDIN™ Retard Tablets 100 mg?

You must not take TRAMUNDIN™ Retard Tablets 100 mg

- in the case of intolerance to tramadol or one of the other ingredients;
- in the case of acute intoxication due to alcohol, analgesics, sleeping medication or other psychotropic drugs (drugs with effects on mood, frame of mind and emotional life);
- if you are at the same time taking MAO inhibitors (certain drugs that act against depression) or if you have taken such medication within the last 14 days before the treatment with TRAMUNDIN™ Retard Tablets 100 mg (see Interactions).

TRAMUNDIN™ Retard Tablets 100 mg must not be used as replacement medication in drug-withdrawal treatment.

When may you take TRAMUNDIN™ Retard Tablets 100 mg only after consulting your doctor?

Listed below are various situations in the presence of which you may take TRAMUNDIN™ Retard Tablets 100 mg only under certain conditions and only with particular caution. Please ask your doctor about this. This also applies if these situations have already arisen earlier.

In the following situations, TRAMUNDIN™ Retard Tablets 100 mg may be used only if all the necessary precautionary measures are taken.

- dependence on other analgesics (opioids);
- disorders of consciousness due to unknown causes, shock;
- conditions with raised intracranial pressure, head injuries or diseases of the brain;
- breathing difficulties (disorders of the respiratory centre and the respiratory function);
- epilepsy or a tendency to convulsions;
- patients who react sensitively to other opioids.

What do you have to consider during pregnancy and lactation?

If you are pregnant or are breast-feeding, your doctor will prescribe TRAMUNDIN™ Retard Tablets 100 mg only if there are compelling reasons for doing so. Tramadol crosses the placental barrier. There is no adequate data available on the use of TRAMUNDIN™ Retard Tablets 100 mg during pregnancy. Repeated administration of tramadol in pregnancy can lead to tramadol habituation in the unborn child and consequently to withdrawal symptoms in the newborn. TRAMUNDIN™ Retard Tablets 100 mg should therefore not be used during pregnancy.

When given before or during the birth, tramadol does not affect the ability of the uterus to contract, which is important for the natural birth process. In the newborn it can lead to changes in the respiratory rate which are, however, as a rule not clinically significant.

About 0.1% of the dose passes into the mother's milk. For this reason, TRAMUNDIN™ Retard Tablets 100 mg should not be taken during the period of lactation. After one single dose of tramadol it is as a rule not necessary to stop breast-feeding.

What has to be taken into account in the case of children and elderly patients?

TRAMUNDIN™ Retard Tablets 100 mg is not intended for use in children with a body weight of less than 25 kg (see also Dosage Instructions).

In the elderly, the dosing interval can be increased (see Dosage Instructions).

Precautionary measures for administration and warnings

What precautionary measures have to be taken?

If in the past you have had unpleasant side effects during treatment with TRAMUNDIN™ Retard Tablets 100 mg or with similar analgesics (opioids), TRAMUNDIN™ Retard Tablets 100 mg should be used with caution.

Convulsions have been reported after tramadol has been taken in the recommended dosage. An increased risk can occur with the administration of dosages in excess of the recommended daily dose of 400 mg. With the simultaneous administration of drugs that lower the convulsion threshold, tramadol can increase the risk of convulsions (see Interactions). Patients with epilepsy or who have a tendency to convulsions should be treated with tramadol only in exceptional, compelling cases.

What do you have to consider when driving a motor vehicle or operating machinery and when working at a workplace without secure support?

TRAMUNDIN™ Retard Tablets 100 mg can affect the powers of reaction to an extent that you may no longer be able to react sufficiently fast and correctly to sudden, unexpected events. If you have the feeling that your powers of reaction are impaired, do not drive a car or any other motor vehicle, do not use electrical tools or operate machinery and do not engage in work where there is no secure support! You should take special note that this applies particularly at the start of the treatment, when drugs are changed and in association with alcohol or other drugs, which also affect the brain and further impair your ability to drive!

Warning!

Please bear in mind that TRAMUNDIN™ Retard Tablets 100 mg can lead to psychic and physical dependence. With prolonged use the effect of TRAMUNDIN™ Retard Tablets 100 mg can become weaker, so that larger amounts of the drug have to be taken (development of drug tolerance). In patients with a tendency to drug abuse or drug dependence, treatment with TRAMUNDIN™ Retard Tablets 100 mg should be given only for short periods and under strict medical supervision.

Interactions with other drugs and other substances

Which other drugs affect the action of TRAMUNDIN™ Retard Tablets 100 mg or are themselves affected by this drug?

Substances	Type of interaction
MAO inhibitors (drugs that act against depression)	Life-threatening interactions affecting the central nervous system, the respiratory system and the circulation have been observed after administration of the analgesic pethidine (opioid). These effects cannot be excluded after the concomitant ingestion of TRAMUNDIN™ Retard Tablets 100 mg.
Alcohol or drugs that also act on the brain	Aggravation of the side effects of tramadol involving the brain, especially impairment of the respiration.
Drugs containing carbamazepine (against epileptic seizures)	Reduction of the analgesic effect. Shortening of the duration of action.
Mixed agonists/antagonists (e.g. buprenorphine, nalbuphine, pentazocine)	Weakening of the analgesic effect of tramadol
Drugs that themselves induce convulsions or lower the convulsion threshold (e.g. drugs for the treatment of certain manifestations in psychiatric illnesses, such as serotonin-uptake inhibitors, tricyclic antidepressants or neuroleptics)	In very rare cases, epileptic are observed.

Please bear in mind that these data can apply also for drugs that have been used shortly before the start of the treatment with TRAMUNDIN™ Retard Tablets 100 mg.

Dosage instructions, mode and duration of application

The following information is valid unless TRAMUNDINTM Retard Tablets 100 mg has been otherwise prescribed for you by your doctor. Please keep to the dosage instructions, as otherwise TRAMUNDINTM Retard Tablets 100 mg cannot work correctly.

How much TRAMUNDINTM Retard Tablets 100 mg should you take, and how often?

The dosage should be adapted to the severity of the pain and to the response of the individual patient to the treatment.

Adults and adolescents from the age of 12 years:

1-2 TRAMUNDINTM Retard Tablets 100 mg tablets twice a day, mornings and evenings (equivalent to 200-400 mg tramadol hydrochloride per day). The retard tablets are divisible, so that individual single doses of 50 mg, 100 mg, 150 mg and 200 mg tramadol hydrochloride in retard form are available.

In principle, the lowest effective analgesic dose should be chosen. A total daily dose of 400 mg active substance should not be exceeded, unless there are special medical reasons for so doing. The interval between doses must not be less than 8 hours.

Dosage in children

TRAMUNDINTM Retard Tablets 100 mg is not intended for use in children with a body weight of under 25 kg and as a rule does not allow for an individual dosage in children under 12 years of age. The treatment should therefore be switched over to more suitable drug forms.

Geriatric patients

In elderly patients (up to the age of 75 years) without signs of severe liver or kidney disease, an adjustment of the dose is as a rule unnecessary. In older patients (over 75 years), however, excretion of the drug may be prolonged. The dosage intervals should therefore also be prolonged, if necessary, in the individual patients.

Severe liver or kidney disease (insufficiency)/Patients on dialysis

In acute pain, TRAMUNDINTM Retard Tablets 100 mg is taken only once or just a few times, so that adjustment of the dose is not necessary. TRAMUNDINTM Retard Tablets 100 mg should not be administered to patients with severe hepatic or renal insufficiency. In less severe cases, a lengthening of the dosage intervals should be considered.

How and when should you take TRAMUNDINTM Retard Tablets 100 mg?

You should take the retard tablets with a little liquid (about half a glass of water) between meals. For the treatment of chronic pain you should take the tablets according to a fixed schedule, as instructed by your doctor (e.g. in the morning at 8.00 hrs and in the evening at 20.00 hrs). The interval between two single doses must not be less than 8 hours.

For how long should you take TRAMUNDINTM Retard Tablets 100 mg?

You should not take TRAMUNDINTM Retard Tablets 100 mg for longer than prescribed for you by your doctor.

Overdosage and other incorrect use

What is to be done if TRAMUNDINTM Retard Tablets 100 mg has been taken in too large amounts (deliberate or accidental overdose)?

If you inadvertently take a single dose of TRAMUNDINTM Retard Tablets 100 mg twice, this as a rule has no negative effects. You should continue to take the TRAMUNDINTM Retard Tablets 100 mg as prescribed, but not until after an interval of 8 hours.

Ingestion of excessive amounts of the drug leads to disturbances of consciousness, to the point of coma (deep unconsciousness), generalised severe epileptic seizures, fall in blood pressure, increased heart rate, contracted or dilated pupils and decreased respiration, to the point of respiratory arrest.

If these signs appear you should call the nearest available doctor for help!

Instruction for your doctor:

In the case of an overdose, a drug that acts against opioids (e.g. naloxone) is given, whereby care has to be taken to ensure that this drug is administered in repeated, small doses, as its duration of action is shorter than that of tramadol. Also after an overdose the patient should be treated in intensive care (particularly with intubation and artificial respiration). Benzodiazepines are suitable in the case of convulsions. Protection against heat-loss and volume-replacement therapy (intravenous administration of fluids to support the circulation) may also be necessary. Gastric lavage can be helpful. TRAMUNDINTM Retard Tablets 100 mg is only slightly dialysable. For this reason, haemodialysis or haemofiltration (systemic lavage) alone are not suitable for the detoxication.

What must you consider if you have taken too little TRAMUNDINTM Retard Tablets 100 mg or if you have forgotten a dose?

If you forget to take a dose your pain may appear again. If this happens do not take twice the normal dose, but continue with the normal prescribed dosage.

What must you consider if you wish to interrupt the treatment or stop it prematurely?

If you interrupt the treatment with TRAMUNDINTM Retard Tablet 100 mg or stop it prematurely, this leads to renewed appearance of the pain.

In the case of unpleasant side effects your doctor will discuss with you what countermeasures can be taken and whether other drugs can be considered for your treatment.

Side effects

What side effects can appear with the use of TRAMUNDINTM Retard Tablets 100 mg?

Nausea and dizziness are common side effects. Vomiting, constipation, sweating, dry mouth, headache and drowsiness sometimes occur.

In rare cases the circulatory regulation can be affected (palpitations, increased heart rate, feeling of weakness and circulatory collapse). This can occur especially when in the standing position and with physical exertion.

Gastrointestinal discomfort (e.g. pressure over the stomach, feeling of fullness) or cutaneous symptoms (e.g. itching, rash, urticaria) can also occur in rare cases.

Very rarely, motor weakness (reduced muscle strength), changes of appetite and disorders of miction have been observed.

Also in very rare cases, TRAMUNDINTM Retard Tablets 100 mg can have various types of psychic side effects, which can differ from individual to individual, depending on personality and on the length of the treatment, e.g. changes of mood (mostly raised, sometimes also agitated mood), changes in activity (mostly subdued, sometimes increased) and change of the cognitive and sensory efficiency (change of sensory perception and recognition, which can lead to errors in decision making).

Allergic reactions (e.g. dyspnoea, "wheezing" respiratory sounds, asthma, accumulation of water in the tissue) and shock reactions (sudden circulatory collapse) have occurred in very rare cases.

Epileptic seizures have also been observed very rarely. They occurred mainly after the use of a high dosage of tramadol or after the concomitant use of drugs that can themselves cause convulsions or that lower the convulsion threshold (e.g. antidepressants or neuroleptics [both types of drugs for the treatment of certain manifestations in psychiatric diseases]).

Very rarely, raised blood pressure and a slowing down of the heart rate (bradycardia) have been observed.

A reduction of the respiration (respiratory depression) has been observed, if the recommended amounts of the drugs are exceeded or if other drugs that have a depressant effect on the brain are administered concomitantly, a reduction of the respiration can occur.

If TRAMUNDINTM Retard Tablets 100 mg is taken over a long period dependence can develop, although the risk of this happening is slight. However, after-effects may then appear after the drug is stopped. These after-effects can include: states of agitation, anxiety, nervousness, sleep disorders, hyper-activity, trembling and gastrointestinal discomfort.

If you should have side effects that are not mentioned in this package leaflet, please tell your doctor or your pharmacist.

What countermeasures should be taken in the event of side effects?

If you experience signs of one or more of the serious side effects described above you should call the nearest available doctor for help. In the event of other unwanted effects, please speak to the doctor who is treating you regarding the further treatment.

Instructions and information on the shelf life of the drug

The expiry date for the contents of this package are printed on the carton box and on the blister-pack containing the tablets. Do not use the contents of the package after that date.

How should TRAMUNDINTM Retard Tablets 100 mg be stored?

The tablets should be kept in a dry place and below 30 °C!

Status of the information

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Keep out of reach of children