Package Leaflet: Information for the User
Tramapine 100 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 Tramapine 100 mg Prolonged-release Tablets are and what they are used for.
2. What you need to know before you take Tramapine 100 mg Prolonged-release Tablets.
3. How to take Tramapine 100 mg Prolonged-release Tablets.
4. Possible side effects.
5. How to store Tramapine 100 mg Prolonged-release Tablets.
6. Contents of the pack and other information.

1. What Tramapine 100 mg Prolonged-Release Tablets are and what they are used for

Tramadol - the active substance in Tramapine 100 mg Prolonged-release Tablets 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.
Tramapine 100 mg Prolonged-release Tablets are used for the treatment of moderate to severe pain.

2. What you need to know before you take Tramapine 100 mg Prolonged-Release Tablets

Do not take Tramapine 100 mg Prolonged-release Tablets:
- 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 MAO-inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with Tramapine 100 mg Prolonged-release Tablets (see "Other medicines and Tramapine 100mg Prolonged-release Tablets").
- 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 Tramapine 100 mg Prolonged-release Tablets 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.
  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 Tramapine 100 mg Prolonged-release Tablets may lead to physical and psychological addiction. When Tramapine 100 mg Prolonged-release Tablets are taken for a long time, their 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 Tramapine 100 mg Prolonged-release Tablets 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 Tramapine 100 mg Prolonged-release Tablets treatment or if they applied in the past.

Other medicines and Tramapine 100 mg Prolonged-release Tablets:
Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines.
Tramapine 100 mg Prolonged-release Tablets should not be taken together with MAO-inhibitors (certain medicines for the treatment of depression).
The pain relieving effect of Tramapine 100 mg Prolonged-release Tablets 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 killers).
- Ondansetron (prevents nausea)

Your doctor will tell you whether you should take Tramapine 100 mg Prolonged-release Tablets and 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 Tramapine 100 mg Prolonged-release Tablets at the same time. Your doctor will tell you whether Tramapine 100 mg Prolonged-release Tablets are suitable for you.
- if you are taking certain antidepressants. Tramapine 100 mg Prolonged-release Tablets 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 Tramapine 100 mg Prolonged-release Tablets. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- If you take tranquillisers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramapine Prolonged-release Tablets. You may feel drowsier or feel that you might faint. If this happens tell your doctor.

Tramapine 100 mg Prolonged-release Tablets with food and drink:
Do not drink alcohol during treatment with Tramapine 100 mg Prolonged-release Tablets as its effect may be intensified. Food does not influence the effect of Tramapine 100 mg Prolonged-release Tablets.

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.
There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use Tramapine 100 mg Prolonged-release Tablets if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.
Generally, the use of Tramapine 100 mg Prolonged-release Tablets is not recommended during breast-feeding. Small amounts of tramadol are secreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

Driving and using machines:
Tramapine 100 mg Prolonged-release Tablets 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 other vehicle, do not use electric tools or operate machinery.

3. How to take Tramapine 100 mg Prolonged-Release Tablets

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 dosage is:

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

Use in children
Tramapine 100 mg Prolonged-release Tablets are not suitable for children below the age of 12 years.

Elderly Patients
In eldery 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 Tramapine 100 mg Prolonged-release Tablets. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take Tramapine 100 mg Prolonged-release Tablets?
Tramapine 100 mg Prolonged-release Tablets are for oral use. Always swallow Tramapine 100 mg Prolonged-release 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 Tramapine 100 mg Prolonged-release Tablets?
You should not take Tramapine 100 mg Prolonged-release Tablets 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 Tramapine 100 mg Prolonged-release Tablets and at what dose.
If you have the impression that the effect of Tramapine 100 mg Prolonged-release Tablets is too strong or too weak, talk to your doctor or pharmacist.

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If you take more Tramapine 100 mg Prolonged-release Tablets 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 Tramapine 100 mg Prolonged-release Tablets
If you forgot 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 Tramapine 100 mg Prolonged-release Tablets
If you interrupt or finish treatment with Tramapine 100 mg Prolonged-release Tablets 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 Tramapine 100 mg Prolonged-release Tablets is stopped. However, on rare occasions, people who have been taking Tramapine 100 mg 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 confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, hallucinations, delusions, paranoia or feeling 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 the 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 Tramapine 100 mg Prolonged-release Tablets, 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 can-not 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 Tramapine 100 mg Prolonged-release Tablets 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 particularly occur in patients 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: hallucinations, confusion, sleep disorders, anxiety and nightmares.
Psychological complaints may appear after treatment with Tramapine 100 mg Prolonged-release Tablets. 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 judgement. Dependence may occur.

Eye disorders
rare: 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) come in very rare cases.

If Tramapine 100 mg Prolonged-release 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 Tramapine 100 mg Prolonged-release Tablets").

Reporting of side effects
If you get any 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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tramapine 100 mg Prolonged-Release Tablets

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 Tramapine 100 mg Prolonged-release Tablets contains:
The active substance is: tramadol hydrochloride
- 1 tablet of Tramapine 100 mg Prolonged-release Tablets contains 100 mg tramadol hydrochloride.

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

What Tramapine 100 mg Prolonged-release Tablets looks like and contents of the pack:
Tramapine 100 mg Prolonged-release Tablets are off white, round biconvex tablets, they are available in 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:
Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary.

Manufacturers:
Farmaceutisch Analytisch Laboratorium Duiven BV, Dijkgraaf 30, 6921 RL Duiven, The Netherlands or
Medochemie Ltd, Facility A – Z, Ayios Athanassios Industrial St, Limassol, Cyprus.

This medicinal product is authorised in the Member States of the EEA under the following names:
NL: Tramadol HCl Retard 100 mg, 150 mg, 200 mg
CY: Mabron Retard 100 mg, 150 mg, 200 mg
IE: Tramapine 100 mg, 150 mg, 200 mg Prolonged-release tablets
LT: Mabron Retard 100 mg, 150 mg, 200 mg
MT: Mabron Retard 100 mg, 150 mg, 200 mg
SE: Tramadol SR Medartuum 100 mg, 150 mg, 200 mg
UK: Tramulief SR 100 mg, 150 mg, 200 mg Tablets

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PINEWOOD HEALTHCARE

Client	Pinewood		Colours used:
Date	28/05/14	■	Black 100%
Product	Tramapine Pil		
Pack Code	24LF01236PD		
Scale	1:1		
Dimensions	185 x 305		
Software	Illustrator CS3		
Proof No	1		
Contact	Louise Foley		Minimum Text 7pt