PACKAGE LEAFLET: INFORMATION FOR THE USER

Tramake 50mg Tablets
Tramake 100mg Tablets
Tramadol Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:

1. What Tramake Tablets are and what they are used for
2. Before you take Tramake Tablets
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1. WHAT TRAMAKE TABLETS ARE AND WHAT THEY ARE USED FOR

Tramake Tablets are one of a group of medicines called analgesics or painkillers. They are used to treat and prevent severe pain.

2. BEFORE YOU TAKE TRAMAKE TABLETS

Do not take Tramake Tablets if you
- are allergic (hypersensitive) to tramadol hydrochloride or any of the other ingredients (for a full list of ingredients see Section 6)
- are taking monoamine oxidase inhibitor (MAOI) antidepressants (examples include moclobemide, tranylcypromine, phenelzine and isocarboxazid) or if you have taken this medicine in the last two weeks
- are taking buprenorphine, nalbuphine or pentazocine (strong pain killers)
- are pregnant, planning to become pregnant or breast-feeding
- have recently taken alcohol, sleeping tablets, other strong pain killers or medicines to treat mental illness
- suffer from epilepsy (fits) that is not adequately controlled by treatment

Check with your doctor or pharmacist before taking Tramake Tablets if you
- have epilepsy or are at risk of seizures (fits)
- are undergoing treatment to withdraw from the use of narcotics
- have suffered a head injury or have raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- are in shock (may cause you to feel cold, clammy, faint or light-headed)
- have liver or kidney problems
- have a condition where you breathe more slowly and weakly than expected (respiratory depression)
- are going to have surgery requiring a local anaesthetic

Tolerance, Dependence and Withdrawal
Tramake Tablets may lead to physical and psychological addiction, which may result in withdrawal symptoms once the drug is stopped (See Section 3 for withdrawal symptoms). When Tramake Tablets are taken for a long time, their effects may decrease, so that higher doses have to be taken (tolerance development). Please inform your doctor if one of these problems occurs during Tramake Tablets treatment or if they have applied to you in the past.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, including those medicines obtained without a prescription:
- carbamazepine (a treatment for epilepsy)
- antidepressants (medicines used to treat depression)
- monoamine oxidase inhibitor (MAOI) antidepressants or if you have taken this medicine in the last two weeks
- antipsychotics (medicines used to treat mental illness)
- buprenorphine, nalbuphine or pentazocine (strong pain killers)
- any opioid medicine which includes strong pain killers such as morphine
- coumarin anticoagulants e.g. warfarin (medicines used to prevent blood clots)
- benzodiazepines (medicines used for treating insomnia and/or anxiety)
- barbiturates (medicines used as sleeping tablets, to treat epilepsy or as an anaesthetic)

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 Tramake Tablets at the same time. Your doctor will tell you whether Tramake Tablets are suitable for you.
- if you are taking certain antidepressants. Tramake 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.

Taking Tramake Tablets with food and drink
You should avoid alcohol when taking this product.

Pregnancy and breast-feeding
Do not take Tramake Tablets if you are pregnant, think you may be pregnant or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines
Tramake Tablets may cause drowsiness, blurred vision or dizziness. Do not drive or use machines until you know how they affect you.

Important information about some of the ingredients of Tramake Tablets
This medicinal product contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TRAMAKE TABLETS

Tramake Tablets should be taken orally (by mouth).

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 Tramake Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Doses:
Adults and children aged 12 years and over:
Tramake 50mg Tablets: the usual dose is one to two tablets taken every four to six hours.
Tramake 100mg Tablets: the usual dose is one tablet taken every four to six hours.

Doctors sometimes prescribe different doses to this. Read the pharmacist's label, it will tell you exactly how many you should take.

Do NOT take more than 400mg in one 24-hour period.

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 (i.e. increasing the length of time between doses).

Children under 12 years:
Tramake Tablets are not recommended in children under the age of 12.

Severe liver or kidney disease (insufficiency)/dialysis patients:
Patients with severe liver and/or kidney insufficiency should not take Tramake Tablets without consulting their doctor. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval (i.e. increasing the length of time between doses).

If you take more Tramake Tablets than you should
It is always important to follow the dose recommended on the label. If you take too many tablets, contact your nearest hospital casualty department or doctor immediately.

If you forget to take Tramake Tablets
If you forget to take a dose take your dose as soon as you remember and then carry on as before. It is important that you do not take a double dose to make up for the forgotten dose.

If you stop taking Tramake Tablets
Some patients may experience withdrawal effects if they suddenly stop taking the tablets. They may develop agitation, anxiety, nervousness, difficulty sleeping, overactivity, tremor and stomach upset. Talk to your doctor before you stop taking the tablets and follow their advice.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramake Tablets can cause side effects, although not everybody gets them.

Contact your doctor at once if you experience:
- an allergic reaction**:** itching, skin rashes, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing, narrowing of airways
- worsening of existing asthma or slowed breathing
- shock (may cause you to feel cold, clammy, faint or light-headed) or collapse

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Very common side effects (affecting more than 1 in 10 users):
dizziness
feeling or being sick

Common side effects (affecting fewer than 1 in 10 users):
increased sweating
tiredness, sleepiness, drowsiness
headache, stomach ache
dry mouth
constipation

Uncommon side effects (affecting fewer than 1 in 100 users):
itching
urticaria/hives
fainting
fast heart beat
dizziness on standing up due to low blood pressure

Rare side effects (affecting fewer than 1 in 1000 users):
effects on mood (extreme sense of wellbeing, euphoria)
confusion
hallucinations (sensing things that are not real)
sleeping problems (including nightmares)
fits

blurred vision
slow heart beat
high blood pressure
changes in appetite
difficulty urinating or inability to urinate
tingling or numbness, for example in the hands and feet ('pins-and-needles')

Very rare side effects (affecting fewer than 1 in 10,000 users):
flushing

Not known (cannot be estimated from the available data):
changes in liver enzyme levels (detected through blood tests)
blood disorders e.g. low blood cell counts
decrease in blood sugar level
rash
effects on mood (low mood, dysphoria)
abuse, withdrawal and dependence

It is important that you do not take tramadol for any longer than your doctor thinks is necessary. There have been reports of people becoming dependent on tramadol or experiencing withdrawal symptoms when they stop taking it. Let your doctor know if you experience any of the possible withdrawal symptoms (see Section 3 'If you stop taking Tramake Tablets').

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517;
Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRAMAKE TABLETS

Keep out of the reach and sight of children.

Store this product below 25ºC.

Do not use Tramake Tablets after the expiry date, which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Do not use Tramake Tablets if you notice that the pack or any of the tablets are damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tramake Tablets contain

- The active substance in Tramake Tablets is tramadol hydrochloride.
  - Tramake 50mg Tablets contain 50mg of tramadol hydrochloride.
  - Tramake 100mg Tablets contain 100mg of tramadol hydrochloride.

- The other ingredients are lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What Tramake Tablets look like and contents of the pack

Tramake 50mg Tablets are white uncoated tablets marked "T50" on one side, the other side is plain and unmarked. They are available in packs of 1, 2, 3, 4, 6, 9, 10, 12, 20, 21, 30, 60, 84, 90, 100, 250, 500 and 1000

Tramake 100mg Tablets are white uncoated tablets marked "TRAMAKE 100" on one side, the other side is plain and unmarked. They are available in packs of 1, 2, 3, 4, 6, 9, 10, 12, 20, 21, 30, 60, 84, 90, 100, 250, 500 and 1000.

Not all pack sizes may be marketed. *(Delete this section as appropriate)*

Marketing Authorisation Holder

Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer

Almac Pharma Services Limited
Almac House
20 Seagoe Industrial Estate
Craigavon
BT63 5QD
UK

This leaflet was last revised in March 2015.

The following date should be inserted below the in-house PX code on the mock-up: "03/02/15"