

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 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 Tramake is and what it is used for
2. What you need to know before you take Tramake
3. How to take Tramake
4. Possible side effects
5. How to store Tramake
6. Contents of the pack and other information

1. What Tramake is and what it is used for

Tramake is one of a group of medicines called analgesics or painkillers. It is used to treat and prevent severe pain.

2. What you need to know before you take Tramake

Do not take Tramake:

- if you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you 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
- if you are taking buprenorphine, nalbuphine or pentazocine (strong pain killers)
- if you are pregnant, planning to become pregnant or breast-feeding
- if you have recently taken alcohol, sleeping tablets, other strong pain killers or medicines to treat mental illness
- if you suffer from epilepsy (fits) that is not adequately controlled by treatment.

Warnings and precautions

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.

Sleep-related breathing disorders

Tramake 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.

Talk to your doctor, pharmacist or nurse if you experience any of the following symptoms while taking Tramake: 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.

Talk to your doctor, pharmacist or nurse before taking Tramake:

- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see ‘Other medicines and Tramake’).
- if you have epilepsy or are at risk of seizures (fits)
- if you are undergoing treatment to withdraw from the use of narcotics
- if you have suffered a head injury or have raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- if you are in shock (may cause you to feel cold, clammy, faint or light-headed)
- if you have liver or kidney problems
- if you have a condition where you breathe more slowly and weakly than expected (respiratory depression)
- if you are going to have surgery requiring a local anaesthetic.

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’).

Tolerance, dependence and withdrawal

Tramake 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 is taken for a long time, the effects may decrease, so that higher doses have to be taken (tolerance development). Please inform your doctor if one of these problems occurs during treatment with Tramake or if they have applied to you in the past.

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 Tramake

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those listed below:

- 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 at the same time. Your doctor will tell you whether Tramake is suitable for you.
- if you are taking certain antidepressants, Tramake may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').

Concomitant use of Tramake and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression) and 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 Tramake 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.

Tramake with food, drink and alcohol

You should avoid alcohol when taking this product.

Pregnancy, breast-feeding and fertility

Tramake should not be taken if you are pregnant, think you may be pregnant or are 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.

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

Driving and using machines

Tramake may cause drowsiness, blurred vision or dizziness. Do not drive or use machines until you know how it affects you.

Tramake contains lactose

Lactose is a type of sugar. 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

Tramake 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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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 is 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 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 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

If you forget to take a dose take your dose 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 Tramake

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).

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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor immediately 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):

- 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 Tramake').
- 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
- hiccups.

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').

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 HPRAs Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Tramake

Keep this medicine out of the sight and reach of children.

Store this product below 25°C.

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

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 protect the environment.

6. Contents of the pack and other information

What Tramake contains

The active substance 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 looks 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 Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Co Louth
A91 P9KD
Ireland

Manufacturer

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

Almac Pharma Services (Ireland) Limited
Finnabair Industrial Estate
Dundalk
Co Louth
A91 P9KD
Ireland

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