

Package leaflet: information for the user

Tramadol HCl capsule CF 50 mg, capsules

tramadol hydrochloride

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Tramadol HCl capsule CF 50 mg and what is it used for?

Tramadol – the active substance in Tramadol HCl capsule CF 50 mg – is a painkiller that belongs to the class of opioids that act on the central nervous system. It relieves pain by acting on certain nerve cells in the spinal cord and the brain.

Tramadol HCl capsule CF 50 mg is used for:

- treatment of moderate to severe pain.

When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6.
- In case of acute poisoning by alcohol, sleeping pills, painkillers, or other psychotropic drugs (drugs that affect mood and emotions).
- You are also using monoamine oxidase inhibitors (MAO inhibitors, medicines for the treatment of depression).
- You have taken MAO inhibitors in the two weeks before you want to start taking Tramadol HCl capsule CF 50 mg.
- You have epilepsy and your epileptic seizures are not adequately controlled by treatment.
- You want to use this medicine as a substitute in a withdrawal treatment.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before you take this medicine. Tell your doctor:

- If you are prone to epilepsy or epileptic seizures, because the risk of a seizure may increase. Normal doses of Tramadol HCl capsule CF 50 mg can cause epileptic seizures. Higher doses of Tramadol HCl capsule CF 50 mg can increase the risk of epileptic seizures. The risk of epileptic seizures is also higher when Tramadol HCl capsule CF 50 mg is used in combination with other medicines (see "Are you taking any other medicines?").
- If you have a head injury.
- If the pressure in your skull is higher than normal. This can be the case after a head injury or can be caused by a brain disease such as a brain tumor.
- If you are in shock (symptoms of shock include cold sweat).
- If you have breathing problems.
- If you have consciousness disorders (if you feel like you are going to faint).
- If you suffer from a severe liver or kidney disorder.
- If you think you are addicted to other painkillers (opioids).
- If you suffer from depression and are using antidepressants, as some of these drugs may interact with tramadol (see 'Are you taking any other medicines?').

Contact your doctor or pharmacist if you experience the following symptoms while using Tramadol HCl capsule CF 50 mg:

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. Your doctor will decide if you need to take hormone supplements.

There is a small risk that you may experience a so-called serotonin syndrome, which can occur after using tramadol alone or in combination with certain antidepressants. Consult a doctor immediately if you experience any of the symptoms of this serious syndrome (see section 4 'Possible side effects').

Sleep-related breathing disorders

Tramadol HCl capsule CF 50 mg can cause sleep-related breathing disorders, such as sleep apnea (pauses in breathing during sleep) and sleep-related hypoxemia (low oxygen levels in the blood). Possible symptoms include: pauses in breathing during sleep, waking up at night due to shortness of breath, difficulty staying asleep, or excessive daytime sleepiness. If you or someone else notices these symptoms, contact your doctor. Your doctor may consider a dose reduction.

Tramadol is converted in the liver by an enzyme. Some people have a variation of this enzyme, which can affect them in different ways. In some people, pain relief may be insufficient, while others may experience severe side effects. If you notice one or more of the following symptoms, you should stop taking the medication and consult a doctor immediately: slow or shallow breathing, confusion, drowsiness, constricted pupils, nausea or vomiting, constipation, and lack of appetite.

Children and adolescents up to 18 years

Use in children with breathing problems

Tramadol is not recommended for children with breathing problems, as the symptoms of tramadol poisoning can be more severe in these children.

Tolerance, dependence, and addiction

This medicine contains tramadol, which belongs to a group of strong painkillers called opiates. Repeated use of opiates can lead to the medicine becoming less effective (you become accustomed to it; this is also known as tolerance). Repeated use of Tramadol HCl capsule CF 50 mg can also lead to dependence, misuse, and addiction, which can result in a life-threatening overdose. The risk of these side effects may increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel like you have no control over how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may be at greater risk of becoming dependent on or addicted to Tramadol HCl capsule CF 50 mg if:

- You or someone in your family has ever misused or been addicted to alcohol, prescription medicines, or illegal drugs ('addiction').
- You smoke.
- You have ever had mood problems (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following symptoms while using Tramadol HCl capsule CF 50 mg, it may be a sign that you are dependent or have become addicted:

- You need to take the medication longer than your doctor has advised.
- You need to take more than the recommended dose.
- You use the medication for reasons other than prescribed, for example, 'to stay calm' or 'to help you sleep'.
- You have made repeated, unsuccessful attempts to stop using the medication or to control its use.
- When you stop taking the medication, you feel unwell and feel better when you take the medication again ('withdrawal symptoms').

If you notice any of these symptoms, contact your doctor to discuss the best treatment plan for you. This should include discussing when the right time is to stop and how to stop safely (see section 3, If you stop taking this medication).

Are you taking any other medications?

Are you taking any other medications besides Tramadol HCl capsule CF 50 mg, have you done so recently, or is there a possibility that you will take other medications in the near future? If so, tell your doctor or pharmacist.

DO NOT take Tramadol HCl capsule CF 50 mg in combination with monoamine oxidase inhibitors (MAO inhibitors), or 2 weeks before and after taking these medications. MAO inhibitors are medications used for depression.

The effect of Tramadol HCl capsule CF 50 mg may be greater if:

- you are taking other medications that affect the central nervous system, such as sedatives, sleeping pills, other painkillers like morphine and codeine (also as a cough medicine)
- you drink alcohol (see also "Driving and using machines").

You may become drowsy or feel like you are going to faint. If this is the case, you should warn your doctor.

The pain-relieving effect of Tramadol HCl capsule CF 50 mg may be reduced and shorter-lasting if:

- you are taking medications that contain ondansetron (for nausea)
- you are also taking carbamazepine (a medication for epilepsy and mental disorders).

You must not use Tramadol HCl capsule CF 50 mg in combination with the following painkillers:

- buprenorphine
- nalbuphine
- pentazocine

The risk of side effects increases

- if you take medications that can cause seizures (fits), such as certain medications for the treatment of depression or psychosis. The risk of having a seizure may increase if you use Tramadol HCl capsule CF 50 mg at the same time. Your doctor will tell you if Tramadol HCl capsule CF 50 mg is suitable for you.
- if you use certain antidepressants; Tramadol HCl capsule CF 50 mg may interact with these medications and you may experience serotonin syndrome (see section 4 'Possible side effects').
- If you use gabapentin or pregabalin for the treatment of epilepsy or pain due to nerve problems (neuropathic pain)

You should be cautious if you also use blood-thinning medications (e.g., warfarin). Tramadol HCl capsule CF 50 mg can prolong your blood's clotting time and cause bruising in the skin (ecchymosis).

If you use ondansetron – a medication for nausea and vomiting – you may need to take more Tramadol HCl capsule CF 50 mg. Your doctor will determine the dose. Ondansetron is often used in cancer treatment (chemotherapy) or before or after surgery.

Concurrent use of Tramadol HCl capsule CF 50 mg and sedative medications such as benzodiazepines or related drugs increases the risk of drowsiness, breathing problems (respiratory depression), coma, and can be life-threatening. Therefore, concurrent use should only be considered if other treatment options are not possible.

However, if your doctor prescribes Tramadol HCl capsule CF 50 mg together with sedative medications, the dose and duration of concurrent treatment should be limited by your doctor. Inform your doctor about all sedative medications you are using and follow your doctor's dosage recommendation closely. It may be helpful to inform friends or family members about the signs and symptoms mentioned above. Contact your doctor if you experience such symptoms.

What should you be aware of with food, drink, and alcohol?

Do not drink alcohol during treatment with Tramadol HCl capsule CF 50 mg as this may enhance the effect. Food does not affect the effect of Tramadol HCl capsule CF 50 mg.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

Pregnancy

There is little information about the safety of Tramadol HCl capsule CF 50 mg in pregnant women.

This medicine can harm your unborn child. If you plan to become pregnant or are already pregnant,

- you may only use Tramadol HCl capsule CF 50 mg if your doctor deems it necessary. Your doctor will decide if you can use Tramadol HCl capsule CF 50 mg.

If your doctor decides that you may use Tramadol HCl capsule CF 50 mg during pregnancy, he/she will only give a few doses. You should not use Tramadol HCl capsule CF 50 mg for a long time during pregnancy. This could affect your unborn child in such a way that it may experience withdrawal symptoms.

Breastfeeding

Tramadol is excreted in breast milk. For this reason, you should not take Tramadol HCl capsule CF 50 mg more than once during the breastfeeding period. If you use Tramadol HCl capsule CF 50 mg more than once, you should stop breastfeeding.

Driving and using machines

Tramadol HCl capsule CF 50 mg can cause drowsiness, dizziness, and blurred vision and can therefore impair your reaction time. If you feel that your reaction time is reduced, do not drive a car or other vehicle, do not use electrical tools, and do not operate machines.

Tramadol HCl capsule CF 50 mg contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Do you have any questions? Then contact your doctor or pharmacist.

Before you start the treatment and at regular intervals during the treatment, your doctor will discuss with you what to expect from using Tramadol HCl capsule CF 50 mg, when and how long you should take it, when you should contact your doctor, and when you should stop using it (see also section 2).

The dose is adjusted to the severity of your pain and your personal sensitivity to pain. In general, the lowest dose that relieves the pain should be used.

Do not take doses more often than once every 4 hours.

The pain-relieving effect of Tramadol HCl capsule CF 50 mg lasts 4 to 8 hours, depending on the severity of your pain.

Your doctor will treat you with Tramadol HCl capsule CF 50 mg for short periods with regular breaks. This keeps the risk of addiction (see "When should you be extra careful with this medicine?") as low as possible.

Do not take more than a total of 400 mg tramadol hydrochloride (8 hard capsules of Tramadol HCl capsule CF 50 mg) per day unless your doctor has explicitly prescribed otherwise.

Use in children under 12 years

Children under 12 years should not use Tramadol HCl capsule CF 50 mg capsules. There are other forms of Tramadol HCl CF that are more suitable for children.

Adults and adolescents over 12 years

The usual single dose is 1-2 capsules of Tramadol HCl capsule CF 50 mg (equivalent to 50-100 mg tramadol hydrochloride) 3 to 4 times a day.

If pain relief is still insufficient 30-60 minutes after taking 1 capsule (50 mg) of Tramadol HCl capsule CF 50 mg, a second single dose of 1 capsule Tramadol HCl capsule CF 50 mg (50 mg) may be administered.

In case of severe pain, your doctor will decide whether 2 capsules of Tramadol HCl capsule CF 50 mg (equivalent to 100 mg tramadol hydrochloride) should be taken. If pain relief is still not achieved, your doctor will increase your dose of Tramadol HCl capsule CF 50 mg until adequate pain relief is achieved.

Elderly patients

In elderly patients (over 75 years), the excretion of tramadol may be delayed. If this applies to you, your doctor may advise increasing the interval between doses.

Patients with severe liver and/or kidney disease (insufficiency) / dialysis patients

Patients with severe liver and/or kidney disease should not use Tramadol HCl capsule CF 50 mg. If there is mild or moderate insufficiency, your doctor may advise increasing the interval between doses.

Method of administration

You should take your Tramadol HCl capsule CF 50 mg whole with water. Do not crush or chew the capsules. You should take Tramadol HCl capsule CF 50 mg between meals.

Duration of treatment

Your doctor will tell you how long you may take Tramadol HCl capsule CF 50 mg.

Have you taken too much of this medicine?

If you accidentally take an extra dose, it generally has no negative effects. You should then take your next dose as prescribed.

After taking very high doses, you may experience severely constricted pupils, vomiting, low blood pressure, rapid heartbeat, fainting, disturbed consciousness up to coma (deep unconsciousness), epileptic seizures, and breathing difficulties up to respiratory arrest. In such cases, contact your doctor immediately or go to the nearest emergency department!

Do not forget to take the packaging and any remaining capsules with you.

Your doctor will treat the symptoms of overdose with Tramadol HCl capsule CF 50 mg.

Have you forgotten to take this medicine?

Do not stop taking the medicine suddenly unless your doctor tells you to do so. If you want to stop taking this medicine, discuss it first with your doctor, especially if you have used the medicine for a long time. Your doctor will tell you when and how you can stop, for example by gradually reducing the dose to minimize the risk of unnecessary side effects (withdrawal symptoms).

If you forget to take the capsules, the pain will probably return. If you forget to take your dose of Tramadol HCl capsule CF 50 mg, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

If you interrupt or stop the treatment with Tramadol HCl capsule CF 50 mg too quickly, the pain is likely to return. If you want to stop the treatment due to unpleasant effects, tell your doctor.

In general, there are no after-effects when treatment with Tramadol HCl capsule CF 50 mg is stopped. However, in rare cases, people who have taken Tramadol HCl capsule CF 50 mg for a long time may feel unwell for a while if they stop taking the medicine abruptly. They may feel agitated, anxious, nervous, or shaky. They may be hyperactive, and have sleep problems and stomach or intestinal problems. A very small number of people may experience panic attacks, hallucinations, unusual sensations such as itching, tingling, and numbness, as well as ringing in the ears (tinnitus). In very rare cases, other unusual symptoms of the central nervous system have been observed, namely confusion, delusions, changes in the perception of one's own personality (depersonalization), changes in the perception of reality (derealization), and paranoia. If you experience any of these complaints after stopping Tramadol HCl capsule CF 50 mg, consult your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them.

Stop using the medicine and contact your doctor immediately if you experience symptoms of an allergic reaction, such as:

- swelling of the face, legs, arm, tongue, larynx, or throat
- difficulty swallowing
- breathing problems
- hives and breathing problems

Very common (occur in more than 1 in 10 users):

- nausea
- dizziness

Common (occur in less than 1 in 10 users):

- vomiting
- constipation

- dry mouth
- headache
- sweating
- drowsiness
- fatigue

Sometimes (occur in less than 1 in 100 users):

- nausea
- gastrointestinal irritation (a feeling of pressure in the stomach, bloating)
- diarrhea
- dysregulation of the cardiovascular system, including feeling your heartbeat (palpitations), rapid heartbeat (tachycardia), dizziness or fainting when standing up (orthostatic hypotension), when blood circulation is insufficient due to poor heart function (cardiovascular collapse)
- The risk of these side effects is higher if you are physically stressed. For example, if you have recently had surgery.
- skin reactions including:
 - itching (pruritus)
 - skin rash
 - hives (urticaria)

Rarely (occur in less than 1 in 1000 users):

- changes in appetite
- slow heartbeat (bradycardia)
- increase in blood pressure
- slow or shallow breathing (respiratory depression). You may experience respiratory depression if:
 - you take much more than the recommended dose (see section 3 "Have you taken too much of this medicine")
 - you take other substances that have a depressant effect on the central nervous system (see "Are you taking any other medicines?")
- seizures. The risk of this is higher:
 - after high doses of Tramadol HCl capsule CF 50 mg or
 - after taking medicines that cause seizures or increase the risk of seizures. Examples include medicines for depression or psychotic symptoms (see "Are you taking any other medicines?").
- muscle twitching
- tingling (paresthesia)
- trembling (tremor)
- psychological complaints may occur after administration of tramadol. These vary in severity and form depending on:
 - your personality
 - how long you have been using Tramadol HCl capsule CF 50 mg.

These problems include:

- mood changes – usually euphoria, sometimes an unpleasant mood
- (dysphoria)
- changes in activity (usually someone becomes less active, sometimes more active)
- changes in the ability to think and feel things properly (your cognitive and sensory ability), for example:

- making decisions (decision-making behavior)
- lack of awareness or understanding (perceptual disorders)
- seeing, hearing, or feeling things that are not there (hallucinations)
- confusion
- sleep disorders
- being confused (delirium)
- nightmares
- blurred vision
- muscle weakness
- difficulty or pain when urinating, passing less urine than normal
- uncoordinated movements
- temporary loss of consciousness (syncope)
- feelings of anxiety
- allergic reactions (hypersensitivity), including:
 - shortness of breath (dyspnea)
 - narrowing of the lower airways causing breathing problems (bronchospasm)
 - wheezing
 - angioedema/severe allergic reactions/shock with breathing difficulties

At the end of the application of the medication, when the treatment is abruptly stopped, withdrawal symptoms may occur (see "If you stop taking this medicine").

Very rare (occur in less than 1 in 10,000 users):

- addiction to the medication
- increase in liver enzyme values

Unknown (cannot be determined with the available data):

- serotonin syndrome, which may manifest as mood changes (e.g., agitation, hallucinations, coma) and other effects, such as fever, rapid heartbeat, unstable blood pressure, involuntary muscle twitching, muscle stiffness, lack of coordination and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea) (see section 2 'When should you not take this medicine or be extra careful?').
- worsening of asthma has been reported, although it has not been established whether this was caused by tramadol
- severely dilated pupils (mydriasis)
- speech disorders
- low blood sugar level, with symptoms such as hunger, sweating, dizziness and/or palpitations (hypoglycemia)
- hiccup

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep this medicine out of the sight and reach of children. Store this medicine in a safe and well-sealed place, where others cannot access it. It can cause serious harm and be fatal to people for whom it is not prescribed.

Do not use this medicine after the expiry date. This can be found on the box and the blister pack. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is tramadol hydrochloride.

One capsule Tramadol HCl capsule CF 50 mg contains 50 mg tramadol hydrochloride.

The other substances in this medicine are: Contents of the capsules

- calcium hydrogen phosphate dihydrate
- magnesium stearate
- colloidal anhydrous silica

Capsule shell

- gelatin
- titanium dioxide (E171)
- sodium lauryl sulfate

What do Tramadol HCl capsule CF 50 mg, capsules look like and how many are in a package?

Tramadol HCl capsule CF 50 mg, capsules: hard, white, opaque capsules.

Tramadol HCl capsule CF 50 mg, capsules are packed in aluminum/pvc blister packs (push-through strips).

Packages of Tramadol HCl capsule CF 50 mg, capsules contain 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 200, 250, 500, and 1000 hard capsules.

Not all mentioned package sizes are marketed.

Marketing authorization holder Centrafarm B.V.

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Manufacturer

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Registered in the register under
RVG 27163, Tramadol HCl capsule CF 50 mg, capsules.

This medicine is registered in EEA member states under the following names:

Belgium	Tramadol EG 50 mg
Germany	Tramadol STADA 50 mg Hard Capsules
Denmark	Tadol, capsules, hard 50 mg
Italy	Tramadol EG
Luxembourg	Tramadol-EG CPS 50 mg
Netherlands	Tramadol HCl capsule CF 50 mg, capsules
Sweden	Tramadol Stada, capsule, hard 50 mg

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