

Package leaflet: Information for the user

Tramadol HCl drops CF 100 mg/ml, drops for oral administration

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 drops CF and what is it used for?

Tramadol – the active substance in Tramadol HCl drops CF – 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 drops CF is used for:

- treatment of moderate to severe pain.

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

When may you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients 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 drops CF.
- 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 take it. 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 drops CF can cause epileptic seizures. Higher doses of Tramadol HCl drops CF can increase the risk of epileptic seizures. The risk of epileptic seizures is also higher when Tramadol HCl drops CF 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 drops CF:

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 drops CF can cause sleep-related breathing disorders, such as sleep apnea (breathing pauses during sleep) and sleep-related hypoxemia (low blood oxygen levels). Possible symptoms include: breathing pauses 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 in others, there may be 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 cause the medicine to become less effective (you become accustomed to it; this is also known as tolerance). Repeated use of Tramadol HCl drops CF 100 mg/ml 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 drops CF 100 mg/ml 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 drops CF 100 mg/ml, it may be a sign that you have become dependent or 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 includes discussing when the right time is to stop and how to stop safely (see section 3, If you stop taking this medication).

Are you using any other medications?

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

DO NOT take Tramadol HCl drops CF 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 drops CF may be greater if:

- you are using 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 drops CF may be reduced and shorter-lasting if:

- you are using medications containing ondansetron (for nausea).
- you are also using carbamazepine (a medication for epilepsy and mental disorders).

You should not use Tramadol HCl drops CF in combination with the following painkillers:

- buprenorphine
- nalbuphine
- pentazocine

The risk of side effects increases

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

You should be cautious if you are also using blood-thinning medicines (e.g., warfarin).

Tramadol HCl drops CF may prolong your blood clotting time and cause bruising (ecchymosis).

If you are using ondansetron – a medicine for nausea – you may need to take more Tramadol HCl drops CF. Your doctor will determine the dose. Ondansetron is often used in cancer treatment (chemotherapy) or before or after surgery.

Concurrent use of Tramadol HCl drops CF and sedative medicines such as benzodiazepines or related medicines 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 drops CF together with sedative medicines, the dose and duration of concurrent treatment should be limited by your doctor.

Inform your doctor about all sedative medicines 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 pay attention to with food, drink, and alcohol?

Do not drink alcohol during treatment with Tramadol HCl drops CF as this may enhance the effect. Food does not affect the effect of Tramadol HCl drops CF. You should take your drops with water or on sugar (to counteract the bitter taste).

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 medicine.

Pregnancy

There is little information about the safety of Tramadol HCl drops CF in pregnant women.

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

- you should only use Tramadol HCl drops CF if your doctor deems it necessary. Your doctor will decide if you may use Tramadol HCl drops CF.

If your doctor decides that you may use Tramadol HCl drops CF during pregnancy, he/she will only give a few doses. You should not use Tramadol HCl drops CF 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 drops CF more than once during the breastfeeding period. If you use Tramadol HCl drops CF more than once, you should stop breastfeeding.

Driving and using machines

Tramadol HCl drops CF can cause drowsiness, dizziness, and blurred vision, and may therefore impair your reactions. If you feel that your reactions are impaired, do not drive a car or other vehicle, do not use electrical tools, and do not operate machines. These symptoms can be worsened by alcohol or other medications. If you experience these symptoms, you should not drive vehicles or use machines.

Tramadol HCl drops CF contains sucrose, polysorbate 20, and sodium

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking Tramadol HCl drops CF. May be harmful to the teeth.

This medicine contains 1 mg of polysorbate 20 in each ml. Polysorbates in this medicine can alter the effects of other medicines. Consult your doctor or pharmacist if you are taking other medicines.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say, 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 starting treatment and at regular intervals during treatment, your doctor will discuss with you what to expect from using Tramadol HCl drops CF, when and how long you should take it, when to contact your doctor, and when to 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 frequently than once every 4 hours.

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

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

Use in children from 1 to 12 years

The dose for children aged 1 to 12 years depends on body weight. The usual single dose is 4-8 drops of Tramadol HCl drops CF per 10 kg of body weight (This is equivalent to approximately 1 to 2 mg of Tramadol HCl drops CF per kg of body weight.)

The maximum daily dose of 32 drops of Tramadol HCl drops CF per 10 kg of body weight (equivalent to approximately 8 mg per kg of body weight) or a total daily dose of up to 160 drops of Tramadol HCl drops CF (approximately 400 mg tramadol hydrochloride) should not be exceeded unless your doctor has explicitly prescribed otherwise.

The typical doses for different age groups and body weights are shown in the table below.

Age	Body weight	Number of drops
1 year	10 kg	4-8
3 years	15 kg	6-12
6 years	20 kg	8-16
9 years	30 kg	12-24
11 years	45 kg	18-36

Adults and adolescents over 12 years

The usual single dose is 20-40 drops of Tramadol HCl drops CF 3 to 4 times a day. This is equivalent to 3 to 4 times a day 50 to 100 mg Tramadol HCl drops CF.

If pain relief is still insufficient 30-60 minutes after administration of 20 drops (50 mg) of Tramadol HCl drops CF, a second single dose of 20 drops of Tramadol HCl drops CF (50 mg) may be administered.

In case of severe pain, your doctor will decide whether 40 drops of Tramadol HCl drops CF (equivalent to approximately 100 mg tramadol hydrochloride) should be taken. If pain relief is still not achieved, your doctor will increase your dose of Tramadol HCl drops CF until satisfactory pain relief is achieved.

Do not take more than a total of 400 mg tramadol hydrochloride per day, unless your doctor has explicitly prescribed otherwise. This is equivalent to approximately 160 drops.

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 drops CF. If there is mild or moderate insufficiency, your doctor may advise increasing the interval between doses.

Method of administration

You should take Tramadol HCl drops CF with water or on sugar. You should take Tramadol HCl drops CF between meals.

Duration of treatment

Your doctor will tell you how long you may take Tramadol HCl drops CF.

Have you taken too much of this medicine?

If you accidentally took an extra dose, this 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 solution with you.

Your doctor will treat the symptoms of overdose with Tramadol HCl drops CF.

Have you forgotten to take this medicine?

Do not suddenly stop taking the medication unless your doctor tells you to do so. If you want to stop taking this medication, discuss it with your doctor first, especially if you have been using the medication 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 your dose of Tramadol HCl drops CF, 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 medication

If you interrupt or stop the treatment with Tramadol HCl drops CF 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 drops CF is stopped. However, in rare cases, people who have taken Tramadol HCl drops CF for a while may feel unwell for some time if they abruptly stop taking the medication. They may feel agitated, anxious, nervous, or shaky. They may be hyperactive, and have sleep problems and stomach or intestinal issues. 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, such as 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 drops CF, consult your doctor.

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

4. Possible side effects

Like any medication, this medication can have side effects. Not everyone experiences them.

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

- swelling of the face, legs, arms, 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

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 drops CF 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 twitches
- 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 drops CF.

These problems include:

- mood changes – usually euphoria, sometimes an unpleasant mood (dysphoria)
- changes in activity (usually a person 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 consciousness 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 rarely (occur in less than 1 in 10,000 users):

- medication addiction
- increase in liver enzyme values

Not known (cannot be determined from 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 side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you 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. You can find this on the bottle and the box. It states a month and a year. The last day of that month is the expiry date.

Tramadol HCl drops CF can be used for 12 months after the first opening of the bottle.

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. If you dispose of medicines in the correct way, they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is tramadol hydrochloride.

One ml Tramadol HCl drops CF 100 mg/ml, drops for oral administration contains 100 mg tramadol hydrochloride.

The other substances in this medicine are:

- potassium sorbate
- sucrose
- polysorbate 20
- sodium saccharin dihydrate
- peppermint oil (limonene, cineole, menthone, menthofuran, isomenthone, menthyl acetate, menthol, pulegone, carvone)
- anethole

- purified water

What does Tramadol HCl drops CF 100 mg/ml, drops for oral administration look like and what is in a package?

Tramadol HCl drops CF 100 mg/ml, drops for oral administration is a clear, colorless or light yellow solution.

Tramadol HCl drops CF 100 mg/ml, drops for oral administration is packaged in a brown glass bottle with a plastic cap with dropper pipette and a plastic screw cap.

Bottles are available with 10 ml, 20 ml, 30 ml, 50 ml, and 100 ml Tramadol HCl drops CF 100 mg/ml, drops for oral administration. Packages with 3 x 10 ml and 5 x 10 ml and 2x50 ml are also available.

Not all mentioned pack sizes are marketed.

Marketing authorization holder

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Registered in the register under

RVG 27165, Tramadol HCl drops CF 100 mg/ml, drops for oral administration.

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

Belgium Tramadol EG 100 mg/ml

Germany Tramadol STADA 100 mg/ml Tropfen zum Einnehmen, Lösung

Italy Tramadolo EG

Luxembourg Tramadol-EG GTTES 100 mg/1 ml

Netherlands Tramadol HCl drops CF 100 mg/ml, drops for oral administration

This leaflet was last approved in July 2024.

Transtoyou