**Package Leaflet: Information for the patient**

# Tramadol Actavis 50mg capsules, hard

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 the leaflet.

**What is in this leaflet**


## 1. What /.../ are and what they are used for

Tramadol hydrochloride is one of a group of medicines called centrally acting analgesics and are used for the relief of moderate or severe pain.

## 2. What you need to know before you take /…/

**Do not take /.../** if you:
- are **allergic** to tramadol hydrochloride, or any of the ingredients of this medicine (listed in section 6).
- 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**.
- have taken a monoamine oxidase inhibitor (**MAOI**) antidepressant within the last two weeks.
- have **severe liver, kidney** or **lung** (breathing) problems.
- suffer from **epilepsy (fits) not controlled by treatment** from your doctor.
- are **undergoing treatment to withdraw** from use of narcotics.

**Warnings and precautions**
**Talk to your doctor or pharmacist** before taking /…/ if you:
- have been or are presently **addicted to alcohol or any other drug**.
- have **epilepsy** or suffered **head injury** or **raised pressure** in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- have **liver, kidney** or **lung** (breathing) problems which are not severe.
- are in **shock** following a severe injury or blood loss.
- are sensitive to opiates.
- suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and /…/').

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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking /…/:
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.

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').

Sleep-related breathing disorders
/…/ 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.

Tolerance, dependence, and addiction
This medicine contains tramadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of /…/ can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.
Dependence or addiction can make you feel that you are no longer in control of 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 have a greater risk of becoming dependent on or addicted to /…/ if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking /…/, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, If you stop taking /…/).

## Other important warnings:

taking a **painkiller** for **headaches** too often or for too long can make them worse.

## Other medicines and /…/

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

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. Especially:
- Monoamine Oxidase Inhibitors (MAOIs, *e.g.* moclobemide), or have taken these within the last 2 weeks.
- any opioid medicines which include strong pain killers such as morphine, pethidine, buprenorphine, nalbuphine and pentazocine.
- medicines which slow your reactions and breathing down.
- carbamazepine (for epilepsy or nerve pain).
- sleeping tablets.
- cimetidine (for gastric ulcers).
- ketoconazole or erythromycin (for infections).
- ondansetron (to prevent feeling or being sick).
- warfarin (for thinning the blood).
- medicines to treat depression (including fluoxetine, paroxetine, amitriptyline or lofepramine).
- medicines to treat anxiety or mental illness.
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

### 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.

### /…/ with food, drink or alcohol
You are advised **NOT to drink alcohol** with this medicine.
The effects of /…/ are not affected by food.

### Pregnancy, breast-feeding and fertility
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.
There is very little information regarding the safety of tramadol in human pregnancy. Therefore you should not use /…/ if you are pregnant.. Chronic use during pregnancy may lead to withdrawal symptoms in newborns.

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

Based on human experience tramaol is suggested not to influence female or male fertility

### Driving and using machines
/.../ may make you feel drowsy, dizzy or in rare cases blur your vision. This may be made worse if you drink alcohol or take other medicines such as strong painkillers with /…/. Make sure you are not affected before you drive or operate machinery.

## 3. How to take /…/

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using /…/, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

Swallow these capsules **whole with a glass of water** at the same times each day.

**Doses:**
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.

- **Adults and children aged 12 years and over**
  Acute pain (such as after an operation): the recommended dose is one to two capsules three to four times a day. To be taken for as long as prescribed by your doctor.
  Chronic pain (such as that associated with cancer): the recommended dose is one or two capsules at first, then one to two capsules every 4 to 6 hours according to the severity of your pain.

**Take no more than eight capsules (400mg) in any 24 hour period unless told to by your doctor.**

- **Older people:** above 75 years: the excretion of tramadol hydrochloride may be delayed. If this applies to you, your doctor may recommend prolonging the dosage interval.
- **Patients with liver or kidney impairment:** the recommended dose is one to two capsules every 12 hours. Patients with severe liver and/or kidney insufficiency should not take /…/. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.
- **Use in children and adolescents:** not recommended for use in children aged under 12 years.

### How long should you take /.../
You should not take /.../ 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 /.../ and at what dose.
If you have the impression that the effect of /.../ is too strong or too weak, talk to your doctor or pharmacist.

### If you take more /.../ 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.

If you (or someone else) swallow a lot of /.../ at the same time you should go to hospital or call a doctor straight away. Signs of an overdose include very small pupils, being sick, fall in blood pressure, fast heartbeat, collapse, unconsciousness, fits and breathing difficulties or shallow breathing.

### If you forget to take /.../ capsules
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

### If you stop taking /.../ capsules
If you interrupt or finish treatment with /.../ too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.
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).
Generally there will be no after-effects when treatment with /.../ is stopped. However, on rare occasions, people who have been taking /.../ for some time may feel unwell if they abruptly stop taking them. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, hallucinations, 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 personaility (depersonalisation), 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 /.../, 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.
**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 /…/ are nausea and dizziness, which occur in more than 1 in 10 people.

**Very common** (may affect more than 1 in 10 people):
- dizziness, feeling sick (nausea)

**Common** (may affect up to 1 in 10 people):
- headaches, drowsiness, fatigue, constipation, dry mouth, being sick (vomiting), sweating (hyperhidrosis)

**Uncommon (**may affect up to 1 in 100 people):
- effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.
- urge to be sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- skin reactions (e.g. itching, rash)

**Rare** (may affect up to 1 in 1,000 people):
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g. pins and needles), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders. 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.
- changes in appetite
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares
- psychological complaints may appear after treatment with /…/. 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 (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
- drug dependence may occur. When treatment is stopped abruptly, signs of withdrawal may appear (see “If you stop taking /…/ ”).
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- slow breathing, shortness of breath (dyspnoea)
- worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria).

**Very rare** (may affect up to 1 in 10,000 people):
- liver enzyme increased

**Not known** (frequency cannot be estimated from the available data):
- decrease in blood sugar level
- hiccups
- 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 /…/’).

**Reporting of side effects**
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store /…/

Keep out of the sight and reach of children.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not store above 30°C.
Keep the container tightly closed (bottles).
Store in the original package (blisters).
Do not use /.../ after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
Do not throw away this medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What /.../ contain

- The active substance  is tramadol hydrochloride.
- The other ingredients are pregelatinised starch, microcrystalline cellulose (E460), magnesium stearate
- The capsule shell contains gelatin, iron oxide (E172), titanium dioxide (E171), indigo carmine (E132). The printing ink contains shellac glaze, iron oxide black (E172) and propylene glycol.

### What /.../ look like and contents of the pack

/…/ are hard gelatine capsules 14,3 mm in length with green cap marked “C” in black and yellow body marked “TK” in black.

Pack sizes are <[To be completed nationally]>.

### Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

### This leaflet was last revised in <{MM/YYYY}>.

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