Package Leaflet: Information for the patient

Tramadol Retard Actavis 100 mg prolonged release tablets
Tramadol Retard Actavis 150 mg prolonged release tablets
Tramadol Retard Actavis 200 mg prolonged release 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.See section 4.

What is in this leaflet

1. What Tramadol Retard Actavis is and what it is used for

Tramadol Retard Actavis is a pain killer. Tramadol Retard Actavis eases the pain by inhibition of certain chemicals of the central nervous system (in the brain and the spinal cord).

Tramadol Retard Actavis can be used in adults and adolescents over 12 years of age. It is used for the treatment of moderate to severe pain.
Tramadol Retard Actavis is not suitable for children under the age of 12 years.

2. What you need to know before you take Tramadol Retard Actavis

Do not take Tramadol Retard Actavis:
- If you are allergic to tramadol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have recently drunk too much alcohol or taken too many sleeping tablets, pain killers, opiates or any medicines that work via the brain (psychotropic medicines).
- When using certain medicines against depression (so-called MAO-inhibitors) or when these have been used the last 14 days.
- If you suffer from epilepsy that is not controlled by medication
- For the treatment of withdrawal symptoms in drug addicts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Tramadol Retard Actavis**:**
- If you have recently had any head injuries, or an increased pressure in the head (e.g. after an accident).
- If you suffer from disorders of the kidneys or liver (see section 3: How to take Tramadol Retard Actavis).
- If you suffer from difficulty to breathe.
- If you have a tendency towards epilepsy or fits because the risk of a fit may increase. Seizures have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

- If you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol Retard Actavis').
- If you suffer from addiction to opiates.
- If you suffer from shock (cold sweat may be a sign of this).
- If you use other medicines or substances that work via the brain, including alcohol.

Medication overuse headache
After long term treatment (>3 months) headache may develop or aggravate.
When tramadol has been used to treat tension or cluster headache or migraine (which is not a registered use for tramadol) cases have been reported of medication overuse headache (MOH).

Metabolism by the liver
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.

Adrenal insufficiency (low cortisol levels)
Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol Retard Actavis:
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.

Serotonin syndrome
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
Tramadol Retard Actavis 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 Tramadol Retard Actavis 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 Tramadol Retard Actavis 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 Tramadol Retard Actavis, 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 Tramadol Retard Actavis).

Children and adolescents
Tramadol is not recommended in children and adolescents with breathing problems, since the symptoms of tramadol toxicity may be worse in these children and adolescents.

Other medicines and Tramadol Retard Actavis
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Tramadol Retard Actavis at the same time, or within 14 days of taking medicines called monoamine oxidase inhibitors (moclobemide or phenelzine for depression, selegiline for Parkinson’s disease).

Concomitant use of Tramadol Retard Actavis 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 Tramadol Retard Actavis 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, such as tranquillizers and sleeping pills, 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.

Tell your doctor if you are taking, have recently taken or might take gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

The pain relieving effect of Tramadol Retard Actavis may be weakened and/or shortened if you also take medicines containing:
- Carbamazepine (used to treat epilepsy)
- Buprenorphine, nalbuphine, or pentazocine (pain killers)
- Ondansetron (used to stop you feeling sick)

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 Tramadol Retard Actavis at the same time. Your doctor will tell you whether Tramadol Retard Actavis is suitable for you.
- if you are taking certain antidepressants. Tramadol Retard Actavis may interact with these medicines and you may experience serotonin syndrome (see section 4 ‘Possible side effects’).
- if you take Tramadol Retard Actavis at the same time as sedative medicines such as tranquillisers, sleeping pills, antidepressants and strong pain relievers (morphine, codeine, pethidine). You may feel excessively drowsy or feel that you might faint.
- if you take Tramadol Retard Actavis at the same time as blood thinning medicines, such as warfarin. The dose of these medicines may need reducing, otherwise there could be an increased risk of serious bleeding.
- anticonvulsant drugs taken with tramadol can lower the seizure threshold and the risk of convulsions may increase in these patients.

Tramadol Retard Actavis with alcohol
Tramadol Retard Actavis should not be used in combination with alcohol.

Pregnancy and 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.

Pregnancy
Tramadol passes the placenta. There are not enough details known to judge the possible harm in human. Long term treatment during pregnancy may lead to withdrawal symptoms in the newborn after birth, as a consequence of addiction. Therefore tramadol should not be taken during pregnancy. Your doctor will advise you.

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

Driving and using machines
Tramadol Retard Actavis can cause drowsiness and dizziness, and blurred vision. Because of this Tramadol Retard Actavis can affect your ability to drive and operate machinery. This can be intensified by alcohol or by medicine that acts or works via the brain.
Do not drive a car or do other activities that need you to be alert, until you know how tramadol affects you. Please see section 4.'Possible Side Effects' for a full list of possible effects that may impair alertness and coordination.

3. How to take Tramadol Retard Actavis

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 Tramadol Retard Actavis, 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).

Dose
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. The usual dosage is:

Adults and adolescents over 12 years of age
The starting dose is:
Tramadol Retard Actavis 100 mg: one tablet (100 mg tramadol hydrochloride) twice a day.
If this is not sufficient to kill the pain the dose can be increased to:
Tramadol Retard Actavis 150 mg: one tablet (150 mg tramadol hydrochloride) twice a day or
Tramadol Retard Actavis 200 mg: one tablet (200 mg tramadol hydrochloride) twice a day.

If the dose you are prescribed cannot be achieved with this strength tablet, other strengths of this medicinal product are available to achieve the dose.

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.

Severe liver or kidney disease (insufficiency)/dialysis patients

Patients with severe liver and/or kidney insufficiency should not take Tramadol Retard Actavis. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

Method of administration
Tramadol Retard Actavis is a tablet with a special core to let out the active ingredient slowly and long-lasting in the body. Because of this it can take a bit longer before you notice the effect.
Swallow the tablet whole (without chewing or breaking), with a glass of water.
Preferably administer in the morning and evening. The tablets may be taken on an empty stomach or during the meal.

Duration of the treatment with Tramadol Retard Actavis
Your doctor will tell you how long you should use Tramadol Retard Actavis. This depends on the cause of the pain. Do not use Tramadol Retard Actavis any longer than necessary.

If you notice that Tramadol Retard Actavis is too strong or is not enough, talk to your doctor or pharmacist.

If you take more Tramadol Retard Actavis than you should
If you have taken too many Tramadol Retard Actavis you should immediately contact your doctor, nearest hospital or clinic. The possible symptoms that may occur are: pin-point pupils, vomiting, a fall in blood pressure, a fast heartbeat, collapse, disturbed consciousness including coma (deep unconsciousness), epileptic fits and difficulties in breathing.

If you forget to take Tramadol Retard Actavis
If you forgot to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking tablets as before.

If you stop taking Tramadol Retard Actavis
If you interrupt or finish treatment with Tramadol Retard Actavis too soon, pain is likely to return. 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 Tramadol Retard Actavis is stopped. However, on rare occasions, people who have been taking Tramadol Retard Actavis tablets 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 noise in the ears (tinnitus). If you experience any of these complaints after stopping Tramadol Retard Actavis, 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, Tramadol Retard Actavis tablets can cause side effects, although not everybody gets them.
The following side effects can occur:

Very common (may affect more than 1 in 10 people):
nausea and dizziness.

Common (may affect up to 1 in 10 people):
headache, vomiting, constipation, dry mouth, sweating, drowsiness, fatique.

Uncommon (may affect up to 1 in 100 people):
heart palpitations, irregular heart beat, low blood pressure – especially when standing up, heart failure (cardiovascular collapse), uneasiness (qualm), pressure on the stomach, feeling of fullness, itch, rash and rash with severe itch and forming of lumps (hives or urticaria), diarrhea.

Rare (may affect up to 1 in 1,000 people):
blurred vision, slower heartbeat than normal, increase in blood pressure, changes in appetite, itch or tingling without cause, shaking, breathing slower than normal, convulsions, hallucinations, confusion, sleep disturbances and nightmares, allergic reactions (e.g. shortness of breath), tightness of the chest by cramp of the muscles of the airways (bronchospasm), gasping, sudden fluid accumulation in the skin and mucosa (e.g. throat or tongue), breathing problems (respiration difficulties) and/or itch and hypersensitiveness. Also reported: mood changes, changes in activity, changes in the observation or the ability to make decisions, muscle weakness, difficulties passing water, involuntary muscle contractions, abnormal coordination, and fainting (syncope).

Not known (frequency cannot be estimated from the available data):
enlarged pupils, 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 Tramadol Retard Actavis').

Side effects that occur at withdrawal, identical to withdrawal symptoms with opiates, can be: agitation, anxiety, fear, nervousness, sleeplessness, difficulty keeping still (hyperkinesias), shaking (tremor) and stomach discomfort (gastro-intestinal disorders).

Allergic reaction (e.g difficulty in breathing, wheezing, swelling of skin), shock (sudden circulation failure) and increase in liver enzyme values have occurred in very rare cases (affects less than 1 user in 10,000). **You should see a doctor immediately if you experience symptoms such as swollen face, tongue and/or throat and/or difficulty to swallow or hives together with difficulties in breathing.**

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

5. How to store Tramadol Retard Actavis

Keep this medicine 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 use this medicine after the expiry date which is stated on the blister and / or bottle and the carton after "exp". The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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 Tramadol Retard Actavis contains:

The active substance is tramadol hydrochloride.
1 tablet of Tramadol Retard Actavis 100 mg, contains 100 mg tramadol hydrochloride
1 tablet of Tramadol Retard Actavis 150 mg, contains 150 mg tramadol hydrochloride
1 tablet of Tramadol Retard Actavis 200 mg, contains 200 mg tramadol hydrochloride

The other ingredients are: calcium hydrogen phosphate dihydrate (E341), hydroxypropyl cellulose (E463), colloidal anhydrous silica (E551), and magnesium stearate (E470b).

What Tramadol Retard Actavis looks like and contents of the pack

Tramadol Retard Actavis 100 mg tablets are off white, round biconvex tablets
Tramadol Retard Actavis 150 mg tablets are off white, capsule shaped tablets
Tramadol Retard Actavis 200 mg tablets are off white, capsule shaped tablets

Tramadol Retard Actavis 100 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.
Tramadol Retard Actavis 150 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.
Tramadol Retard Actavis 200 mg: packs of 10, 20, 30, 50, 60, 90, 100, 120, 180 or 500 off white tablets in blisters or in plastic tablet containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer:

<[To be completed nationally]>

Manufacturers:
<[To be completed nationally] >

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Tramadol Retard Actavis
Austria	Tramadolhydrochlorid Actavis 100 mg, 150 mg, 200 mg Retardtabletten
Czech Republic	Tramadol Retard Actavis 100 mg
Sweden	Tramadol Retard Actavis
Slovakia	Tramadol Retard Actavis 100 mg, 150 mg, 200 mg

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