PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S5**

TRAMADOL UNIMED (50 mg capsules)

Tramadol hydrochloride

Sugar free

Please read this leaflet carefully before you are given TRAMADOL UNIMED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRAMADOL UNIMED has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRAMADOL UNIMED is and what it is used for

Tramadol hydrochloride is the active ingredient in TRAMADOL UNIMED.

It is a painkiller belonging to the class of opioids that acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

TRAMADOL UNIMED is used for the treatment of moderate to severe pain.

2. What you need to know before you take TRAMADOL UNIMED

Do not take TRAMADOL UNIMED:

- If you are hypersensitive (allergic) to tramadol or any of the other ingredients of TRAMADOL UNIMED (listed in section 6),
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions),
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression) or have taken them in the last 14 days before treatment with TRAMADOL UNIMED (see "Other medicines and TRAMADOL UNIMED "),
- if you are an epileptic
- as a substitute in narcotic withdrawal.
- if you have difficulty in breathing
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease).
- if you are pregnant or breastfeeding
- if you or your child are younger than 18 years of age and you or your child have had an operation to remove your tonsils or adenoids.
- if you or your child are younger than 12 years of age

Warnings and precautions

TRAMADOL UNIMED are not suitable for children under the age of 12 years

It should not be used in the treatment of minor pain.

Special care should be taken with TRAMADOL UNIMED

- if you think that you are addicted to other pain relievers (opioids) because TRAMADOL UNIMED may lead to physical and psychological addiction. When TRAMADOL UNIMED is taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development).

  Please also inform your doctor if one of these problems occurs during TRAMADOL UNIMED treatment or if they applied to you in the past.
- if you are sensitive to addictive substances (opiates).

- if you are taking other centrally depressant medicines. Respiratory depression (slow and ineffective breathing) may develop if TRAMADOL UNIMED are given concomitantly with other centrally depressant medicines.
- if you are in a state of shock (cold sweat may be a sign of this).
- if you suffer from a liver or kidney disease, as the elimination of TRAMADOL UNIMED is delayed 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 TRAMADOL UNIMED and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.
- if you have a history of mental health disorders (difficulty in thinking, understanding and judging clearly which causes loss of touch with reality), if you have depression, anxiety and suffer from alcohol or drug abuse.

Sleep-related breathing disorders

TRAMADOL UNIMED contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example
central sleep apnoea (shallow/pause of breathing during sleep) and sleep- related hypoxemia (low level of oxygen in the blood).
The risk of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnoea.

Epilepsy or seizures

Tell your doctor if you are suffering from epilepsy or are susceptible to seizures as TRAMADOL UNIMED is not recommended in the presence of these conditions (see ‘Do not take TRAMADOL UNIMED’ above).

Children

TRAMADOL UNIMED capsules are not suitable for children younger than 12 years of age.

Other medicine and TRAMADOL UNIMED

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- TRAMADOL UNIMED should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).
- The pain-relieving effect of TRAMADOL UNIMED may be reduced and the length of time it acts may be shortened, if you take medicines which contain carbamazepine (for epileptic fits).
- TRAMADOL UNIMED might decrease the anti-nausea effect of ondansetron and increase the requirement for TRAMADOL UNIMED in patients with postoperative pain. if you are taking other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking TRAMADOL UNIMED. you may feel drowsier or feel that you might faint. Concomitant use of TRAMADOL UNIMED and tranquillizers or sleeping pills (e.g. benzodiazepines), 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 prescribes TRAMADOL UNIMED together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating medicines you are taking and follow your doctor’s dose recommendation closely.
- if you are taking medicines which may cause convulsions (fits), such as certain tricyclic antidepressants, antipsychotics or other threshold lowering medicine. The risk having a fit may increase if you take TRAMADOL UNIMED at the same time.
- if you are taking certain medicine that stimulate serotonin (chemical that contributes to happiness) receptors, TRAMADOL UNIMED may interact with these medicines and it may cause serotonin toxicity with symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor,

exaggeration of reflexes, increased muscle tension, body temperature above 38 °C. Withdrawal of the serotonergic medicines usually brings about a rapid improvement.

- if you are taking coumarin anticoagulants (medicines for blood thinning), e.g. warfarin, together with TRAMADOL UNIMED. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- interactions are unlikely to occur with concomitant or previous administration of cimetidine (antacid).
- if you suffer from a liver disease (see “Special care should be taken with TRAMADOL UNIMED”). Ketoconazole (anti-fungal) and erythromycin (antibiotic) inhibit the liver enzymes CYP3A4.

TRAMADOL UNIMED with food and alcohol

Do not drink alcohol during treatment with TRAMADOL UNIMED as its effect may be intensified.

Food does not influence the effect of TRAMADOL UNIMED.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TRAMADOL UNIMED.

There is very little information regarding the safety of tramadol in human pregnancy. Therefore, you should not use TRAMADOL UNIMED if you are pregnant (see Do not use TRAMADOL UNIMED above).

The child may experience withdrawal symptoms after birth.

Tramadol is excreted into breast milk. For this reason, you should not take TRAMADOL UNIMED during breast-feeding, or alternatively, if you take TRAMADOL UNIMED, you should stop breast-feeding (see Do not use TRAMADOL UNIMED above).

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

Driving and using machines

TRAMADOL UNIMED may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate machinery. Do not drive while taking TRAMADOL UNIMED until you know how it affects you.

TRAMADOL UNIMED contains sodium

TRAMADOL UNIMED contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take TRAMADOL UNIMED

Do not share medicines prescribed for you with any other person.

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

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. Do not take more than 8 capsules (400 mg TRAMADOL UNIMED) daily except if your doctor has instructed you to do so.

Adults and children from the age of 12 years

The usual dose is one or two capsules (equivalent to 50 mg – 100 mg tramadol hydrochloride) every 4 – 6 hours.

Your doctor may prescribe a different, more appropriate dosage of TRAMADOL UNIMED if necessary.

The total daily dose of 400 mg of TRAMADOL UNIMED (equivalent of 8 capsules) should not be exceeded.

Children

TRAMADOL UNIMED should not be given to children below the age of 12 years.

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 UNIMED. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

How and when should you take TRAMADOL UNIMED

TRAMADOL UNIMED are for oral use.

Always swallow TRAMADOL UNIMED whole, not divided or chewed, with sufficient liquid, preferably in the morning and evening. You may take the capsule on an empty stomach or with meals.

How long should you take TRAMADOL UNIMED

You should not take TRAMADOL UNIMED 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 TRAMADOL UNIMED and at what dose.

If you have the impression that the effect of TRAMADOL UNIMED is too strong or too weak, tell your doctor or pharmacist.

If you take more TRAMADOL UNIMED than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

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 TRAMADOL UNIMED

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

If you stop taking TRAMADOL UNIMED

If you interrupt or finish treatment with TRAMADOL UNIMED too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects.

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 UNIMED is stopped. However, on rare occasions, people who have been taking TRAMADOL UNIMED 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 personality (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 TRAMADOL UNIMED, 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

TRAMADOL UNIMED may have side effects.

Not all side effects reported for TRAMADOL UNIMED are included in this leaflet. Should your general health worsen of if you experience any untoward effects while receiving TRAMADOL UNIMED, please inform your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking TRAMADOL UNIMED and tell your doctor immediately or go to the casualty department at your nearest hospital:

- symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing together with difficulties in breathing.
- hives

These are all very serious side effects. If you have them, you may have had a serious reaction to TRAMADOL UNIMED. You may need urgent medical attention or hospitalisation

The most common side effects during treatment with TRAMADOL UNIMED are nausea and dizziness, which occur in more than 1 in 10 people.

Tell your doctor if you notice the following:

Frequent side effects:

- headaches, drowsiness
- fatigue
- constipation, dry mouth, being sick (vomiting)
- sweating (hyperhidrosis).

Less frequent side effects:

- 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 sick (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea
- abdominal pain, inflammation of the pancreas (pancreatitis)
- skin reactions (e.g. itching, rash)
- 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. itching, tingling, numbness), 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.
- hallucination, confusional state, sleep disorders, delirium, anxiety and nightmares.
- psychological complaints may appear after treatment with TRAMADOL UNIMED. 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 TRAMADOL UNIMED”).
- blurred vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down (respiratory depression).
- weak muscles
- passing urine with difficulty or pain, passing less urine than normal (dysuria).
- hepatic enzyme increased
- decrease in blood sugar level

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TRAMADOL UNIMED.

5. How to store TRAMADOL UNIMED

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in the outer container until required for use.

Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TRAMADOL UNIMED contains

The active ingredient is tramadol hydrochloride 50 mg per capsule.

The other ingredients are:

Capsule powder: colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

Capsule shell: gelatin, water, sodium lauryl sulphate, indigo carmine (E132), iron oxide yellow (E172), titanium dioxide (E171).

What TRAMADOL UNIMED looks like and contents of the pack

Yellow/green size 4 hard gelatin capsules filled with white to off-white powder.

Pack sizes: 20 capsules in a printed cardboard carton (2 PVC/PVdC aluminium foil blister packs of 10 capsules each).

100 capsules in a printed cardboard carton (10 PVC/PVdC aluminium foil blister packs of 10 capsules each).

HOLDER OF THE CERTIFICATE OF REGISTRATION

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