PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

DOLOTRAM CAPSULES, 50 mg

Tramadol hydrochloride

Contains sugar (lactose monohydrate): 145,5 mg per capsule.

Read all of this leaflet carefully before you start taking DOLOTRAM CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DOLOTRAM CAPSULES 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 DOLOTRAM CAPSULES is and what it is used for

The active substance is tramadol hydrochloride.

DOLOTRAM CAPSULES is used for the management of moderate to severe pain.

2. What you need to know before you take DOLOTRAM CAPSULES

Do not take DOLOTRAM CAPSULES:

- If you are hypersensitive (allergic) to tramadol hydrochloride, opioids or to any of the other ingredients of DOLOTRAM CAPSULES (listed in section 6).
- If you are younger than 12 years of age.
- If you are younger than 18 years of age following tonsillectomy (removal of tonsils) and/or adenoidectomy (removal of adenoids which are located at the back of the nasal cavity).
- If you have used alcohol, sleeping medication, medicines for anxiety, pain or depression, or narcotic medications within the past few hours.
- If you have asthma or breathing problems.
- If you are taking monoamine oxidase inhibitors (antidepressant medication) or within two weeks of their withdrawal (see section 2, “Other medicines and DOLOTRAM CAPSULES”).
- If you are on narcotic withdrawal treatment; DOLOTRAM CAPSULES should not be used as a substitute in drug withdrawal.
- If you have difficulty breathing or breathing problems (respiratory depression) especially in the presence of cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes) and excessive bronchial secretions.
- If you have previously had head injuries, brain tumour or if you have a condition in which the pressure in your skull has increased.
- If you have epilepsy not controlled by adequate treatment.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions:

Take special care with DOLOTRAM CAPSULES:

- If you have a history of head injury, epilepsy or other seizure disorder.

- If you have a history of drug or alcohol addiction or if you think that you are addicted to other pain relievers (opioids).
- If you have a metabolic disorder; or if you are also using certain medicines to treat migraine headaches, muscle spasms, depression, mental illness, or nausea and vomiting.
- If you have liver or kidney disease.
- If you are in shock (a condition where there is not enough blood flow through the body).
- If you are younger than 12 years of age, DOLOTRAM CAPSULES should not be used (see section 2, “Children and adolescents”).
- DOLOTRAM CAPSULES can lead to psychological and physical dependence or addiction in some people, especially with long-term use. The dose needed to achieve the desired effect may increase with time. DOLOTRAM CAPSULES should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid painkillers.
- If you have a history of mental health disorder because taking DOLOTRAM CAPSULES may increase your risk of dependence or abuse.
- If you have had convulsions (seizures) or history thereof, because the risk of a seizure may increase or the condition can be made worse, especially if the upper dose limit (400 mg) of DOLOTRAM CAPSULES is exceeded.
- DOLOTRAM CAPSULES works by being converted (metabolised) into its active component. If you convert (metabolise) DOLOTRAM CAPSULES to this active component more rapidly and completely than other patients, you are known as an ultra-rapid metaboliser. If you are an ultra-rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking this medicine and consult your doctor immediately.
- The risk of tramadol hydrochloride (the active ingredient of DOLOTRAM CAPSULES) toxicity may be higher if you are younger than 18 years of age following tonsillectomy (removal of tonsils) and/or adenoidectomy (removal of adenoids which are located at the back of the nasal cavity).
- DOLOTRAM CAPSULES is not recommended in children with breathing problems, since the

symptoms of tramadol hydrochloride (the active ingredient of DOLOTRAM CAPSULES) toxicity may also be worse in these children.

- If you use DOLOTRAM CAPSULES together with sedative medicines (such as benzodiazepines or related medicines), the risk of feeling extremely drowsy or experiencing a difficulty in breathing may occur (see section 2, “Other medicines and DOLOTRAM CAPSULES”).

- Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your health care provider about your treatment.

Sleep-related breathing disorders

DOLOTRAM CAPSULES 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 hypoxaemia (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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking DOLOTRAM CAPSULES. 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 a hormone supplement.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol hydrochloride (the active ingredient of DOLOTRAM CAPSULES) in combination with certain antidepressants or tramadol hydrochloride alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4).

You may experience low levels of sodium in the blood (hyponatraemia) while taking this medicine. Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and

seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking DOLOTRAM CAPSULES, consult your doctor immediately.

Children and adolescents:

DOLOTRAM CAPSULES are not recommended for use in children under the age of 12 years as it is unlikely to be safe (see section 2 “Warnings and precautions”).

Other medicines and DOLOTRAM CAPSULES:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines known to influence the effect of tramadol hydrochloride (as in DOLOTRAM CAPSULES) are:

- Carbamazepine (used for seizures).
- Quinidine (used for heart rhythm disorders).
- Ketoconazole, ritonavir or erythromycin (for treating infections).
- Alcohol.
- Ondansetron (used to prevent feeling or being sick).
- Monoamine oxidase inhibitors (medicines used to treat depression including fluoxetine, paroxetine, amitriptyline or lofepramine), or if you have used this medication within 14 days of stopping such treatment.
- Pentazocine, nalbuphine or buprenorphine (pain killers).
- If you are taking medicines which may cause fits (convulsions), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take DOLOTRAM CAPSULES at the same time. Your doctor will tell you whether DOLOTRAM CAPSULES is suitable for you.
- If you are taking certain antidepressants. DOLOTRAM CAPSULES may interact with these medicines and you may experience serotonin syndrome (see section 4).

- Medicines that prevent blood clotting, such as warfarin; the dose of these medicines may need to be reduced, otherwise there could be an increased risk of potentially serious bleeding.
- Sedative medicines such as sleeping pills, tranquillisers or calming medicines, may lead to increased side effects such as drowsiness and impaired concentration or even result in life-threatening effects.

DOLOTRAM CAPSULES with food, drink and alcohol:

You are advised **NOT to drink alcohol** with DOLOTRAM CAPSULES. The effects of DOLOTRAM CAPSULES are not affected by food.

Pregnancy and breastfeeding:

Do not take DOLOTRAM CAPSULES if you are pregnant, think that you may be pregnant or breastfeeding your baby. It may harm your baby.

If you are pregnant or breastfeeding, think that 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 DOLOTRAM CAPSULES.

Driving and using machines:

Do not drive or operate machinery while taking DOLOTRAM CAPSULES.

Important information about some of the ingredients of DOLOTRAM CAPSULES:

DOLOTRAM CAPSULES contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DOLOTRAM CAPSULES.

3. How to take DOLOTRAM CAPSULES

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

Always take DOLOTRAM CAPSULES exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Doses:

The dosage should be adjusted to the intensity of your pain and individual pain sensitivity. The lowest pain relieving dose should be taken.

The usual dose for adults and children aged 12 years and over:

Your doctor will prescribe the dosage of DOLOTRAM CAPSULES for your condition.

Acute pain (such as after an operation): The usual dose is 50 mg initially, to be taken for as long as prescribed by your doctor.

Chronic pain (such as associated with cancer): The usual dose is 50 mg or 100 mg initially then according to the severity of the pain, as prescribed by your doctor. Do not exceed a dose of more than 400 mg per day (which is the same as 8 DOLOTRAM CAPSULES).

Older people over 75 years of age: The excretion of tramadol may be delayed. The doctor may recommend prolonging the dosage interval.

Patients with liver or kidney impairment: The recommended dose is one or two DOLOTRAM CAPSULES every 12 hours. Patients with severe liver and/or kidney insufficiency should not take DOLOTRAM CAPSULES. If the insuffiency is mild or moderate, the doctor may recommend prolonging the dosage interval.

DOLOTRAM CAPSULES should not be taken longer than necessary. If more is required for treatment, consult with the doctor who will check at regular intervals whether to continue and if so at what dose.

Your doctor will tell you how long your treatment with DOLOTRAM CAPSULES will last. If you have the impression that the effect of DOLOTRAM CAPSULES is too strong or too weak, tell your doctor or pharmacist.

If you take more DOLOTRAM CAPSULES than you should:

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

nearest hospital or poison centre.

The symptoms reported for overdosage are pinpoint or wide pupils, vomiting, slow breathing and heart rate, severe drowsiness, cold and clammy skin, feeling faint, reduced level of consciousness up to coma (deep unconsciousness), epileptic seizures and difficulty in breathing up to stoppage of breathing may occur.

If you forget to take DOLOTRAM CAPSULES:

Skip any missed dose if it is almost time for your next scheduled dose. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

DOLOTRAM CAPSULES can have side effects.

Not all side effects reported for DOLOTRAM CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOLOTRAM CAPSULES, please consult your doctor, pharmacist or other health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash and itching.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty breathing.
- Seizure (convulsions).

- Weak or shallow breathing.
- Difficulty breathing (respiratory depression), or where your airways go into spasm making it difficult to breathe which may cause wheezing or coughing (bronchospasm).
- Fast heart rate.
- Severe low blood pressure with inability to stand without dizziness, and/or severe weakness (cardiovascular collapse).
- Severe skin reaction (blistering of the skin, eyes, lips, mouth and genitals, as these may be due to a serious allergic reaction known as Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis).
- Serotonin syndrome (such as agitation, hallucinations, coma, fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination, nausea, vomiting, diarrhoea).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Dizziness
- Feeling sick
- Sleep disorders
- Headache
- Dry mouth
- Constipation
- Tiredness
- Sleeplessness
- Increased sweating

Less frequent:

- Drowsiness or sleepiness
- Stomach ache or irritation

- Urge to vomit
- Itching, sweating, flushing (warmth, redness, or tingly feeling)
- Wheezing
- Change in appetite
- Hallucinations
- Loss of appetite
- Confusion
- Nightmares
- Delusions
- Anxiety
- Paranoia
- Changes in mood
- Feeling dazed or disconnected from your surroundings
- Overactive reflexes
- Loss of coordination
- Speech disorders
- Blurred vision
- Small pupils (miosis)
- Pupils that are larger than normal (dilated pupils or mydriasis)
- Fast or irregular heartbeats, also called palpitations (dysrhythmia)
- Changes in blood pressure (usually low blood pressure). This might make you feel dizzy or lightheaded
- High blood pressure
- Hiccups
- Muscle weakness
- Micturition disorders (dysuria, difficulty in passing urine and urinary retention), urinary frequency

- Nervousness, feeling anxious, shaking (tremors) and stomach side effects (signs of withdrawal symptoms)

Frequency unknown:

- Itchy rash, itching, hives, lips, tongue, or throat
- Agitation
- Fever
- Nausea
- Vomiting
- Low blood sugar (hypoglycaemia)
- Diarrhoea
- Fainting; fever, sore throat, burning in your eyes, skin pain

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. 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 DOLOTRAM CAPSULES.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically:pharmacovigilance.africasme@sunpharma.com or tel:+27(0) 12 643 2000

5. How to store DOLOTRAM CAPSULES

Store all medicines out of reach of children

Store at or below 25 °C.

Keep blister strips in carton until required for use.

Protect from light and moisture.

Return all unused medicine to your pharmacist.

Do not use after the expiry date printed on the label.

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

6. Contents of the pack and other information

What DOLOTRAM CAPSULES contains:

The active substance is tramadol hydrochloride.

Each capsule contains 50 mg tramadol hydrochloride as active ingredient.

The other ingredients are:

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycollate, starch and talcum.

What DOLOTRAM CAPSULES looks like and contents of the pack:

Capsules, size “2” maroon cap and yellow body containing white powder.

Content of the packaging:

Aluminium blister strip

10 capsules are packed in one aluminium blister strip and 2 or 10 blister strips are packed in each individual outer container with package insert.

AL/PVC cold form blister pack

10 capsules are packed in one cold form blister pack and 2 or 10 blister packs are packed in each individual outer container with package insert.

Not all pack types may be marketed

Pack sizes: 20 or 100.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

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