Patient Information Leaflet for DOLOTRAM 50/100

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DOLOTRAM 50 solution for injection

DOLOTRAM 100 solution for injection

Tramadol hydrochloride

Sugar free

Read all of this leaflet carefully before you are given DOLOTRAM

- 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.

What is in this leaflet:

1. What DOLOTRAM is and what it is used for

Tramadol, the active substance in DOLOTRAM, is a painkiller belonging to the class of the opioids that acts on the central nervous system.

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

2. What you need to know before DOLOTRAM is administered

DOLOTRAM should not be administered to you:

- If you are hypersensitive (allergic) to tramadol hydrochloride or any of the other ingredients of DOLOTRAM listed in section 6.
- 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 (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 are taking monoamine oxidase inhibitors (antidepressant medication) or within two weeks of their withdrawal.
- If you are on narcotic withdrawal treatment; DOLOTRAM should not be used as a substitute in withdrawal.
- If you are pregnant or breastfeeding your baby (see section 2, “Pregnancy and breastfeeding”).
- If you have epilepsy not controlled by adequate treatment.
- 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).

Tell your doctor or health care provider before being administered the injection:

- If you have a history of head injury, epilepsy or other seizure disorder, as the risk of a seizure may increase or the condition can be made worse, especially if the upper dose limit (400 mg) of DOLOTRAM is exceeded.
- If you are in shock (a condition where there is not enough blood flow through the body).
- 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.

Substance abuse and dependence:

DOLOTRAM 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 should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid painkillers.

Increasing the dose of DOLOTRAM can make you more sensitive to pain. If this happens, you need to speak to your health care provider about your treatment.

Ultra-rapid metabolisers:

DOLOTRAM works by being converted (metabolised) into its active component. If you convert (metabolise) DOLOTRAM 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.

Hyponatraemia:

You may experience low levels of sodium in the blood (hyponatraemia) while using DOLOTRAM. 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 using DOLOTRAM, consult your doctor immediately.

Sleep-related breathing disorders:

DOLOTRAM 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.

If you use DOLOTRAM 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”).

Talk to your doctor or pharmacist if you experience any of the following symptoms while receiving DOLOTRAM: 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, consult 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 received tramadol hydrochloride (the active ingredient of DOLOTRAM) 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).

Other:

Special care should be taken with DOLOTRAM if you have liver or kidney disease.

Children and adolescents:

DOLOTRAM is not indicated for children below the age of 12 years or in children younger than 18 years following tonsillectomy (removal of tonsils) and/or adenoidectomy (removal of adenoids which are located at the back of the nasal cavity)(see section 2, “DOLOTRAM should not be administered to you”).

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

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

- Carbamazepine (used for seizures).
- Quinidine (used for heart rhythm disorders) or other CYP2D6 inhibitors such as paroxetine (used for depression).
- Alcohol.
- Ketoconazole (used for fungal infections).
- Erythromycin (used for bacterial infections).
- Monoamine oxidase inhibitors (a type of antidepressant), or if you have used this medication within 14 days of stopping such treatment.
- Ondansetron (used to prevent feeling or being sick).
- If you are taking certain antidepressants. DOLOTRAM 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.

Pregnancy and breastfeeding:

DOLOTRAM should not be used if you are 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 receiving DOLOTRAM.

Driving and using machines:

Do not drive or operate machinery while using DOLOTRAM.

DOLOTRAM may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. Do not drive a car or other vehicle, do not use electric tools or operate machinery until you are sure how DOLOTRAM affects you.

3. How DOLOTRAM will be administered

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

You will not be expected to give yourself DOLOTRAM. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with DOLOTRAM will last. If you have the impression that the effect of DOLOTRAM is too strong or too weak, tell your doctor or pharmacist. Your doctor will adjust your dosage according to the intensity of your pain and your individual pain sensitivity. The lowest pain-relieving dose will be used. A total daily dose of DOLOTRAM should not exceed 400 mg tramadol.

Adults and children older than 12 years of age:

The usual dose is 50 or 100 mg given 4 to 6 hourly as an intravenous, intramuscular or subcutaneous injection.

The doctor may change your dose if you are an elderly patient (above 75 years) or if you suffer from liver and/or kidney insufficiency.

If you receive more DOLOTRAM than you should:

Since a health care provider will administer DOLOTRAM, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive DOLOTRAM:

Since a health care provider will administer DOLOTRAM, it is unlikely that the dose will be missed.

4. Possible side effects

DOLOTRAM can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DOLOTRAM. 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:

- Seizure (convulsions).
- Weak or shallow breathing.
- Agitation.
- Hallucinations.
- Fever.
- Fast heart rate.
- Overactive reflexes.

- Loss of coordination, fainting.
- Severe skin reaction, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.
- Sore throat.
- Burning in your eyes.
- Serotonin syndrome. You may experience symptoms such as muscular rigidity, agitation, hallucinations, coma, fever, increase in heart rate, unstable blood pressure, involuntary twitching, 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:

- Headache.
- Dizziness.
- Drowsiness.
- Feeling tired.
- Constipation.
- Diarrhoea.
- Nausea.
- Vomiting.
- Stomach pain.
- Dry mouth.
- Sweating.

- Flushing (warmth, redness, or tingly feeling).

Less frequent:

- Feeling nervous or anxious.
- Itching.
- Rash.
- Low blood sugar levels.
- Changes in appetite.
- Heartburn.
- Trembling.
- Nightmares.
- Disturbed sleep patterns.
- Difficulty or pain passing water.
- Muscle weakness.
- Blurred vision.
- Withdrawal syndrome.

Frequency unknown:

- Hiccups.
- Confusion.
- Delusions.
- Despersonalisation-derealisation.
- Paranoia.
- Drug dependence.

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 "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DOLOTRAM.

5. How to store DOLOTRAM

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

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 contains:

The active substance is tramadol hydrochloride.

DOLOTRAM 50: Each ampoule contains 50 mg tramadol hydrochloride as active ingredient.

DOLOTRAM 100: Each ampoule contains 100 mg tramadol hydrochloride as active ingredient.

The other ingredients are sodium hydroxide and water for injection.

What DOLOTRAM looks like and contents of the pack:

DOLOTRAM 50: A clear colourless solution filled in 1 mL clear glass OPC ampoule with a yellow ring and blue dot.

DOLOTRAM 100: A clear colourless solution in 2 mL clear glass OPC ampoule with a maroon ring and blue dot.

Pack size:

5 ampoules are packed in a plastic tray per carton.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill, Ext. 1, Roodepoort

Johannesburg 1724

Tel. no.: 011 495 0100

Signed

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