APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

DOLTREX 50 MG film-coated tablet

Tramadol hydrochloride 50 mg

Contains sugar (lactose monohydrate 125.30 mg)

Read all of this leaflet carefully before you start taking DOLTREX 50 MG

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **DOLTREX 50 MG** have 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 **DOLTREX 50 MG** is and what it is used for
2. What you need to know before you take **DOLTREX 50 MG**
3. How to take **DOLTREX 50 MG**
4. Possible side effects
5. How to store **DOLTREX 50 MG**
6. Contents of the pack and other information

1. What DOLTREX 50 MG is and what it is used for

Tramadol, the active substance in **DOLTREX 50 MG** tablets, is a painkiller belonging to the class of the opioids that acts on the central nervous system. It is used for the management of moderate to moderately severe pain.

2. What you need to know before you take or give DOLTREX 50 MG

Do not take or give DOLTREX 50 MG :

- if you are allergic to tramadol or any of the other ingredients of **DOLTREX 50 MG** tablets. (Refer to WHAT **DOLTREX 50 MG** CONTAINS, above);

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- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);

- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with **DOLTREX 50 MG** tablets;

- If you have epilepsy;

- As a substitute in drug withdrawal;

- If you are pregnant or breastfeeding your baby (see Pregnancy and Breastfeeding).

Warnings and precautions

Take special care with **DOLTREX 50 MG**:

Some people will need special care from their doctors when they are taking **DOLTREX 50 MG**. Make sure that your doctor knows before you start taking **DOLTREX 50 MG**:

- if you think that you are addicted to other pain relievers (opioids);

- if you suffer from consciousness disorders (if you have fainting spells or you feel that you are going to faint);

- if you are in a state of shock (cold sweat may be a sign of it);

- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);

- if you have difficulty in breathing;

- if you have a tendency towards epilepsy or seizures because the risk of a seizure may increase; especially if the upper dose limit (400 mg) of **DOLTREX 50 MG** tablets is exceeded;

- if you suffer from a liver or kidney disease.

- Tramadol works by being converted (metabolised) into its active component. If you convert (metabolise) Tramadol 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 with your doctor immediately.

- 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

DOLTREX 50 MG, consult with your doctor immediately **DOLTREX 50 MG** tablets 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. **DOLTREX 50 MG** tablets should be used with caution, and only for short periods under strict medical supervision, in patients who are addicted to other opioid pain-killers.

- **DOLTREX 50 MG** contains sugar (lactose monohydrate). If you have been told by our doctor that you have intolerance to some sugars, contact your doctor before taking **DOLTREX 50 MG**.

Please also inform your doctor if any of these problems occur during **DOLTREX 50 MG** tablets treatment or if they applied to you in the past.

Use in children

DOLTREX 50 MG tablets are not suitable for children under the age of 12 years.

Other medicines and DOLTREX 50 MG

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

The following medicine is particularly important:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

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DOLTREX 50 MG tablets should not be used together with Monoamine oxidase (MAO) inhibitors (certain medicines for the treatment of depression), or within 2 weeks of stopping treatment with this.

- The pain-relieving effect of **DOLTREX 50 MG** tablets may be reduced and the length of time it acts may be shortened if you take medicines which contain:

- Carbamazepine (for epileptic seizures);
- Ondansetron (prevents nausea).

Your doctor will tell you whether you should have **DOLTREX 50 MG** tablets, and at what dose.

The risk of side effects increases,

- If you are taking tranquilisers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while having **DOLTREX 50 MG** tablets. You may feel drowsier or feel that you might faint. If this happens tell your nurse or doctor.
- If you are taking medicines which may cause seizures such as certain antidepressants or antipsychotics. The risk of having a seizure may increase if you take **DOLTREX 50 MG** tablets at the same time. Your doctor will tell you whether **DOLTREX 50 MG** tablets are suitable for you.
- If you are taking certain antidepressants such as Selective Serotonin Reuptake Inhibitors or MAO inhibitors. **DOLTREX 50 MG** tablets may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 ° C.
- If you are taking warfarin together with **DOLTREX 50 MG** tablets. The effect of warfarin on blood clotting may be increased and bleeding may occur.

DOLTREX 50 MG with food and drink:

Do not drink alcohol during treatment with **DOLTREX 50 MG** tablets as the effects of **DOLTREX 50 MG** and alcohol may intensify each other. Food does not influence the effect of **DOLTREX 50 MG** tablets.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **DOLTREX 50 MG** tablets.

If **DOLTREX 50 MG** tablets are used on a long term basis during pregnancy, it will lead to harm (withdrawal symptoms) in newborns.

You should not take **DOLTREX 50 MG** tablets if you are pregnant.

The use of **DOLTREX 50 MG** tablets is not recommended during breastfeeding. **DOLTREX 50 MG** is excreted into breast milk. If you are taking **DOLTREX 50 MG** tablets you should not breastfeed your baby.

Driving and using machines

DOLTREX 50 MG tablets 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 **DOLTREX 50 MG** tablets affect you.

It is not always possible to predict to what extent **DOLTREX 50 MG** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **DOLTREX 50 MG** affects them.

3. How to take DOLTREX 50 MG

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

Always take or give **DOLTREX 50 MG** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of **DOLTREX 50 MG** is too strong or too weak, talk to your doctor or pharmacist.

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

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

Do not take more than 400 mg **DOLTREX 50 MG** tablets daily.

Tablets are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

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The usual dose is:

Adults and patients over 18 years of age:

Moderate pain: Take an initial dose of 50 mg tramadol (1 **DOLTREX 50 MG** capsule), followed by 50 mg or 100 mg every 4 to 6 hours.

Severe pain: Take an initial dose of 100 mg followed by 50 mg or 100 mg every 4 to 6 hours.

You should not take **DOLTREX 50 MG** tablets for longer than is absolutely necessary.

Children (below the age of 12)

DOLTREX 50 MG tablets are not suitable for children under the age of 12 years.

Elderly patients (above 75 years):

A dose reduction and/or prolongation of the interval between doses are recommended.

Liver or kidney disease (insufficiency)/dialysis patients

If you suffer from liver and/or kidney insufficiency, the excretion of **DOLTREX 50 MG** tablets may be delayed. Your doctor may direct you to prolong your dosage intervals.

If you take more DOLTREX 50 MG than you should

- Seek emergency medical attention if you think you have taken too much of **DOLTREX 50 MG**.

If you have taken an additional dose by mistake, this will generally have no negative effects. You should have your next dose as your doctor prescribed it for you.

After taking very high doses, pin-point or wide pupils, vomiting, fall in blood pressure, fast heartbeat, feeling faint, reduced level of consciousness up to coma (deep unconsciousness), epileptic seizures and difficulty in breathing up to stoppage of breathing may occur.

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

If you forget to take DOLTREX 50 MG

If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

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If you stop taking DOLTREX 50 MG

If treatment with **DOLTREX 50 MG** is stopped earlier than your doctor has prescribed, your disease may become worse. Always take **DOLTREX 50 MG** for as long as your doctor has prescribed.

If you interrupt or finish treatment with **DOLTREX 50 MG** tablets too soon, your pain may return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor.

If you have been taking **DOLTREX 50 MG** tablets for some time you may feel unwell if you abruptly stop treatment. You may feel agitated, anxious, nervous or shaky. You may be hyperactive, have difficulty in sleeping and have stomach or bowel disorders. You may get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in ears (tinnitus).

Further unusual Central Nervous System (CNS) symptoms, i.e. confusion, delusion, change in how you see (perceive) your own personality (depersonalisation), and change in how you see (perceive) reality (derealisation) and delusion of persecution (paranoia) have been reported. If you experience any of these effects after you stop taking **DOLTREX 50 MG** tablets, consult your doctor.

4. Possible side effects

DOLTREX 50 MG can have side effects.

Not all the side effects reported for **DOLTREX 50 MG** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **DOLTREX 50 MG**, please consult your healthcare provider for advice.

If any of the following happens, stop taking DOLTREX 50 MG tablets and tell your doctor immediately or go to your casualty department at your nearest hospital:

- swollen face, tongue and/or throat, and/or difficulty swallowing or breathing or wheezing;
- rash, swelling or itching of skin;
- shock (sudden circulation failure).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DOLTREX 50 MG** tablets. 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 or experience any of the following:

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- changes in the way your heart beats, for example, if you notice that your heart is beating faster;
- pounding (this may particularly occur when you are under strain, have a slow heartbeat, an increase in blood pressure or change position from an upright position to sitting or laying down;
- feeling faint;
- loss of consciousness;
- slow breathing;
- shortness of breath;
- seizures (fits);
- passing urine with difficulty or pain, passing less urine than is normal for you.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- dizziness;
- headaches;
- drowsiness;
- nausea (feeling sick urge to vomit);
- vomiting;
- constipation;
- dry mouth;
- sweating more than is normal for you;
- fatigue.

Less frequent side effects

- abnormal sensations for example if you experience itching, tingling, or numbness;
- trembling;
- muscle twitches;
- uncoordinated movement;
- changes in appetite;
- hallucination;

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- confusional state;
- sleep disorders;
- delirium;
- anxiety;
- nightmares;
- changes in mood for example you may feel happy or irritated;
- decreased activity;
- restlessness;
- changes in the way you see or view things;
- blurred vision;
- narrowing of the pupil;
- stomach trouble (e.g. feeling of pressure in the stomach, bloating);
- diarrhoea (frequent or loose watery stools);
- weak muscles;
- liver enzyme increased;
- acute pancreatitis;
- abdominal pain.

The following side effects have been reported in post-marketing surveillance:

- speech disorder;
- excessive widening of your pupils;
- Stevens-Johnson syndrome - a rare, serious **disorder** of the skin and mucous membranes. It starts with flu-like symptoms, followed by a painful rash that spreads and blisters.
- Low levels of sodium in the blood and/or inappropriate antidiuretic hormone secretion (SIADH)
- Increased risk of abdominal pain, including acute pancreatitis. Frequency: rare

If any of the side effects get serious, or if you experience one of the above –mentioned serious side effects, call the nearest doctor immediately. If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If you get 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 to SAHPRA via the "**6.04 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 **DOLTREX 50 MG.**

5. How to store DOLTREX 50 MG

Store at or below 25 °C (room temperature).

Keep the HDPE container closed.

Protect from light and moisture.

Store all medicines out of reach of children.

Store in the original package / container.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

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

6. Contents of pack and other information

What DOLTREX 50 MG contains

Each capsule contains tramadol hydrochloride 50 mg.

Contains lactose.

The other ingredients are: Colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch

glycolate and coating agent containing hypromellose 6 cPs,

polyethylene glycol 400, polysorbate 80 and titanium dioxide.

Contains sugar (lactose).

What DOLTREX 50 MG looks like and contents of the pack

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DOLTREX 50 MG:

White to off-white, capsule shaped, biconvex, film coated tablets debossed with “ML 4” on one side and plain on other side.

HDPE container pack 100’s:

Tablets are packed in a round white opaque plastic container (HDPE) and are closed with a white child resistant closure, packed in an outer carton. Pack sizes include 100 tablets.

Blister Packs 20’s and 100’s:

Clear, transparent PVC 250 µm as the forming material and silver coloured, plain 25 µm aluminium foil/ 6 - 8 gsm HSL in a pre-printed outer carton.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

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