Reg. No 48/2.9/0698

Patient information leaflet for DOLOTRAM PLUS (clean copy)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DOLOTRAM PLUS film-coated tablets

Tramadol hydrochloride 37,5 mg and paracetamol 325 mg.

Sugar free.

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

- 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 PLUS 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 PLUS is and what it is used for

DOLOTRAM PLUS contains tramadol and paracetamol.

Tramadol 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. Paracetamol belongs to the class of analgesics that acts on the central nervous system.

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

Do not take DOLOTRAM PLUS:

- If you are allergic to tramadol, paracetamol, any of the other ingredients mentioned in section 6.1, or other opioids such as codeine.
- If you are suffering from acute alcohol poisoning.
- If you are taking sleeping pills, pain relievers or medicines that affect mood and emotions.
- If you are also taking medicines such as tranylcypromine and moclobemide or have taken them in the last 14 days before treatment with DOLOTRAM PLUS which are used to treat depression. These medicines are used to treat depression and belong to a group called monoamine oxidase inhibitors (MAOIs).
- If you have a severe liver disorder.
- DOLOTRAM PLUS must not be used for narcotic (an addictive substance) withdrawal treatment.
- You should not take DOLOTRAM PLUS if you suffer from severe breathing problems.
- You should not take DOLOTRAM PLUS if you are suffering from increased intracranial pressure or central nervous system depression, which are characterised by decreased rate of breathing, decreased heart rate, and loss of consciousness.
- You should not take DOLOTRAM PLUS if you have fits that are not controlled.

Warnings and precautions

Take special care with DOLOTRAM PLUS:

- If you take other medicines containing paracetamol or tramadol.
- If you have kidney problems.

- If you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick).
- If you are dependent on any other medicines (for example morphine).
- If you have epilepsy or have experienced fits or seizures.
- Tramadol exerts its effect by converting (metabolising) 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. This means 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 DOLOTRAM PLUS and consult with your doctor immediately.
- If you abruptly stop treatment with DOLOTRAM PLUS you may suffer from panic attacks, severe anxiety (feeling nervous or worried), hallucinations (hearing or seeing things that are not there), paraesthesia (burning or prickling sensation that is usually felt in the hands, arms, legs, or feet) and tinnitus (ringing or buzzing in the ears). Your doctor will gradually decrease your dose of DOLOTRAM PLUS to prevent these side effects from occurring.
- DOLOTRAM PLUS contains paracetamol. If you are allergic to paracetamol, you may break out in a severe skin rash after you take DOLOTRAM PLUS. You should stop using DOLOTRAM PLUS at the first appearance of a skin rash or any other sign of allergy.
- DOLOTRAM PLUS should not be taken with alcohol containing beverages.
- While taking DOLOTRAM PLUS you may experience low levels of sodium in your blood (hyponatraemia). Symptoms 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 experience any of these symptoms while taking DOLOTRAM PLUS, consult your doctor immediately.
- If you suffer from sleep-related breathing disorders, take special care when taking DOLOTRAM PLUS.

  Talk to your doctor if you develop a craving for DOLOTRAM PLUS.

- DOLOTRAM PLUS has a low level of sodium per tablet, that is to say essentially 'sodium-free'.

Other medicines and DOLOTRAM PLUS

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

You should not take DOLOTRAM PLUS with the following:

- A group of antidepressants called monoamine oxidase MAO) inhibitors (such as moclobemide and tranylcypromine). When taken together with DOLOTRAM PLUS it can cause diarrhoea, tachycardia (irregular heartbeat), hyperhidrosis (excessive sweating), trembling, confusional state, even coma.
- Carbamazepine (used to treat seizures). When taken together with DOLOTRAM PLUS it can cause reduced efficacy and shorter duration due to decreased concentration of tramadol.
- Buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The effects of these medicines may be decreased.

Caution is advised when the following medicines are given with DOLOTRAM PLUS:

- Tramadol can induce convulsions and increase the potential for certain antidepressants such as citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, antipsychotics and seizure threshold- lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.
- Concomitant therapeutic use of tramadol and citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, moclobemide and tranylcypromine and mirtazapine may cause serotonin toxicity. Symptoms include 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.

- If you are taking other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, or medicines to treat allergies as well as sedative medicines such as benzodiazepines (alprazolam, diazepam, lorazepam) or related medicines with DOLOTRAM PLUS as there is an increased risk of drowsiness, difficulties in breathing (respiratory depression), coma which may be life-threatening.
- If you are taking warfarin (for blood thinning). The effectiveness of DOLOTRAM PLUS may be altered, and bleeding may occur.
- If you are taking digoxin used to treat heart problems.
- If you are taking diflunisal used for pain.
- If you are taking ondansetron used to treat vomiting.

DOLOTRAM PLUS with food and drink

Do not drink alcohol during treatment with DOLOTRAM PLUS as the effects of DOLOTRAM PLUS and alcohol may intensify each other.

Pregnancy, breastfeeding and fertility

DOLOTRAM PLUS must not be taken during pregnancy.

DOLOTRAM PLUS must not be taken during breastfeeding since there is no information available regarding safety during breastfeeding.

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 healthcare professional for advice before taking DOLOTRAM PLUS.

Driving and using machines

Do not drive while taking DOLOTRAM PLUS until you know how it affects you.

DOLOTRAM PLUS can affect your ability to drive as it may make you sleepy or dizzy.

If you feel drowsy while taking DOLOTRAM PLUS, do not drive, use tools or use machinery.

3. How to take DOLOTRAM PLUS

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

Always take DOLOTRAM PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with DOLOTRAM PLUS will last. If you have the impression that the effect of DOLOTRAM PLUS is too strong or too weak, talk to your doctor or pharmacist.

- Swallow the tablets whole with sufficient liquid.
- Do not break or chew the tablets.

Adults:

The recommended dosage is 1 or 2 tablets every 4 to 6 hours, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor.

Do not take more than 8 tablets per day.

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

If you take more DOLOTRAM PLUS than you should

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

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage from too much paracetamol. Your kidneys can also become damaged in the absence of liver damage.

If you forget to take DOLOTRAM PLUS

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DOLOTRAM PLUS

Withdrawal symptoms may occur if DOLOTRAM PLUS is discontinued abruptly. You may experience anxiety, nervous excitement, difficulty sleeping, excessive abnormal movements, tremor and gastrointestinal symptoms.

Other symptoms that have very rarely been seen if tramadol hydrochloride is discontinued abruptly include: panic attacks, severe anxiety, hallucinations, tingling or prickling sensation and ringing in the ears.

4. Possible side effects

DOLOTRAM PLUS can have side effects.

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

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

- Rash or itching all over the body.
- Allergic reactions along with breathing problems or closing of the throat.
- Increased bleeding time.

These are all very serious side effects. If you have them, you may have had a serious reaction to DOLOTRAM PLUS. 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: The following side effects occur frequently**:**

- Irregular heartbeat that is much rapid and more pronounced than usual.

- Elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools , weakness, fatigue.

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:

- Confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).
- Dizziness, excessive sleepiness.
- Headache, trembling.
- Nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas.

Less frequent side effects

- Depression, seeing, hearing, smelling, tasting or imagining things, nightmares.
- Involuntary muscular contractions, tingling or prickling sensation, loss of memory.
- Ringing in the ear.
- Rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia.
- Difficulty swallowing, blood in faeces.
- Chills.
- Chest pain.
- Problems with urination.
- Difficulty breathing.
- Increase in blood pressure, hot flushes.
- Low blood sugar.
- Drug dependence.
- Mental confusion and emotional disruption.
- Convulsions, fainting, speech disorders.

- Slurred speech, stumbling, convulsions, syncope, speech disorders.
- Vision blurred, constriction of the pupil (miosis).
- Excessive dilation of the pupils (mydriasis).

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- Feeling faint when getting up from a lying or sitting position, slow heart rate, fainting.
- Changes in appetite.
- Muscle weakness, slower or weaker breathing.
- Mood changes, changes in activity, changes in perception.
- Worsening of existing asthma.

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DOLOTRAM PLUS.

5. How to store DOLOTRAM PLUS

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the tablets in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton / blister.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOLOTRAM PLUS contains

The active substances in DOLOTRAM PLUS are tramadol hydrochloride and paracetamol.

Each film-coated tablet contains 37,5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are magnesium stearate (E572), maize starch, microcrystalline cellulose (E460), Opadry Yellow (containing hypromellose (E464), iron oxide yellow (colourant) (E172), macrogol (E1521), talc (E553b) and titanium dioxide (E171)), povidone (E1201), pregelatinised starch and sodium starch glycolate.

What DOLOTRAM PLUS looks like and contents of the pack

Light yellow coloured, film-coated, capsule shaped, biconvex tablets, debossed with '537' on one side and plain on the other side.

DOLOTRAM PLUS is packed in a 100 CC white round HDPE bottle with a screw neck, white polypropylene cap and an induction seal.

Pack size: 100 tablets.

Holder of certificate of registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext.1, Roodepoort

Johannesburg

1724

Reg. No 48/2.9/0698

This leaflet was last revised in

June 2023

Registration number

48/2.9/0698