Front Side

400 mm

435 mm

SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE

MAKLODOL 50 mg (Film-coated tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MAKLODOL 50 mg Film-coated tablet
Each film-coated tablet contains tramadol hydrochloride 50,0 mg. Contains sugar (Lactose monohydrate 125,30 mg).
Excipients:
For a full list of excipients, see **section 6.1**

3. PHARMACEUTICAL FORM

Film-coated tablet
MAKLODOL 50 mg film-coated tablet:
White to off-white, capsule shaped, biconvex, film coated tablets debossed with "ML 4" on one side and plain on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Management of moderate to moderately severe pain.

4.2 Posology and method of administration
Posology:
The dosage should be adjusted to the intensity of pain and the sensitivity of the individual patient.
In principle, the lowest pain-relieving dose should be selected. In general, a total oral daily dose of 400 mg of tramadol (equivalent to 8 **MAKLODOL 50 mg** tablets) should not be exceeded.
The recommended dosages are guidelines.
MAKLODOL 50 mg tablets should be taken as follows:
Adults and children over 12 years
Moderate pain:
Initial dose of 50 mg of Tramadol (1 **MAKLODOL 50 mg** tablet), followed by 50 mg or 100 mg 4-6 hourly.
Severe pain:
Initial dose of 100 mg followed by 50 mg or 100 mg 4-6 hourly.
Tablets are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

Special populations:
Paediatric population
On account of the high dosage strength, **MAKLODOL 50 mg** tablets are not intended for children below the age of 12 years.

Elderly patients
A downward adjustment of the dose and/or prolongation of the interval between doses are recommended in the elderly over 75 years.

Patients with renal insufficiency/dialysis
In patients with renal insufficiency, the elimination of tramadol hydrochloride is delayed. In these patients prolongation of the dosage intervals should be carefully considered according to the patient's requirements. In cases of severe renal insufficiency **MAKLODOL 50 mg** tablets are not recommended.

Patients with hepatic impairment
In patients with hepatic insufficiency the elimination of tramadol hydrochloride is delayed. In these patients prolongation of the dosage intervals should be carefully considered according to the patient's requirements. In cases of severe hepatic insufficiency **MAKLODOL 50 mg** tablets are not recommended.

Duration of treatment
Under no circumstances should **MAKLODOL 50 mg** tablets be given for longer than absolutely necessary. If the nature and severity of the disease require long-term pain treatment, careful checks should be carried out initially and at regular intervals to assess efficacy and adverse events and to what extent further treatment with **MAKLODOL 50 mg** tablets is necessary.

Method of administration:
Oral
Tablets are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

4.3 Contraindications
- Known hypersensitivity to tramadol hydrochloride or opioids or any of the ingredients of **MAKLODOL 50 mg**.
- in acute intoxication with alcohol, hypnotics, analgesics, opioids or psychotropic medicines.
- It should not be administered to patients who are receiving monoamine oxidase (MAO) inhibitors or within two weeks of their withdrawal.
- **MAKLODOL 50 mg** tablets should not be given to patients with epilepsy.

MAKLODOL 50 mg tablets must not be used for narcotic withdrawal treatment.
MAKLODOL 50 mg tablets should not be given to patients with respiratory depression, or in the presence of cyanosis and excessive bronchial secretions.
MAKLODOL 50 mg tablets should not be given to patients with increased intracranial pressure or central nervous depression due to head injury or cerebral disease.
MAKLODOL 50 mg tablets should not be used in pregnant and breastfeeding women (see **Section 4.6**).

4.4 Special warnings and precautions for use
MAKLODOL 50 mg tablets may only be taken with special care in opioid dependence.
MAKLODOL 50 mg tablets are not suitable for children under the age of 12 years.
MAKLODOL 50 mg tablets should be used with care in patients with increased reactivity to opioids.
Respiratory depression may develop if the recommended dosages are exceeded or other centrally depressant medicines are given concomitantly.
MAKLODOL 50 mg tablets should not be used in the treatment of minor pain.
MAKLODOL 50 mg tablets should be used with caution in patients with impairment of hepatic and renal function and in patients prone to convulsive disorders or in shock. (see **Section 4.2**).

Seizures
Seizures have been reported in patients receiving **MAKLODOL 50 mg** tablets at dosages within the recommended dosage range. The risk of seizures may be enhanced in patients exceeding the recommended dose, or in patients taking tricyclic antidepressants or other tricyclic compounds e.g. promethazine, selective serotonin reuptake inhibitors, MAO-inhibitors and neuroleptics.

Drug Abuse and Dependence
Tolerance, psychic and physical dependence of the morphine-type (μ opioid) may develop. **MAKLODOL 50 mg** tablets have been associated with craving drug-seeking behaviour and tolerance development. Symptoms of drug withdrawal syndrome, similar to those occurring during opiate withdrawal, may occur as follows: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastro-intestinal symptoms. Other symptoms that have been seen with **MAKLODOL 50 mg** tablets discontinuation include: panic attacks; severe anxiety, hallucinations, paraesthesias, tinnitus and unusual CNS symptoms (i.e. confusion, delusions, depersonalisation, derealisation and paranoia).
MAKLODOL 50 mg tablets should not be used in opioid-dependent patients or in patients with a family history of substance abuse or mental health issues. **MAKLODOL 50 mg** tablets can reinstate physical dependence in patients that have been previously dependent or chronically using other opioids. In patients with a tendency to drug abuse, a history of drug dependence or who are chronically using opioids, treatment with **MAKLODOL 50 mg** tablets are not recommended.

CYP2D6 Ultra-rapid metabolism of tramadol:
Patients who are CYP2D6 ultra-rapid metabolisers may convert tramadol to its active metabolite (M1) more rapidly and completely than other patients. This rapid conversion may lead to higher than expected serum M1 levels which could lead to an increased risk of respiratory depression. Alternative medication, dose reduction and/or increased monitoring for signs of tramadol overdose, such as respiratory depression is recommended in patients known to be CYP2D6 ultra-rapid metabolisers.

Hyponatraemia:
Hyponatraemia has been reported with the use of **MAKLODOL 50 mg**, usually in patients with predisposing risk factors, such as elderly patients and/or patients using concomitant medications that may cause hyponatraemia. This hyponatraemia appeared to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH) and resolved with discontinuation of **MAKLODOL 50 mg** and appropriate treatment (e.g. fluid restriction). During **MAKLODOL 50 mg** treatment, monitoring for signs and symptoms of hyponatraemia is recommended for patients with predisposing risk factors.
Lactose
Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take **MAKLODOL 50 mg.**

4.5 Interaction with other medicines and other forms of interaction
MAKLODOL 50 mg tablets should not be combined with MAO inhibitors within 14 days of withdrawal of MAO inhibitors (see **Section 4.3**).
In patients treated with MAO inhibitors in the 14 days prior to the use of the opioid pethidine, life-threatening interactions of the central nervous system, respiratory and cardiovascular function have been observed. The same interactions with MAO inhibitors cannot be ruled out during treatment with **MAKLODOL 50 mg** tablets.
Concomitant administration of **MAKLODOL 50 mg** tablets with other centrally depressant medicines including alcohol may potentiate the CNS effects (see **Section 4.3**).
Simultaneous or previous administration of carbamazepine (enzyme inducer) may reduce the analgesic effect and shorten the duration of action.
MAKLODOL 50 mg tablets can induce convulsions and increase the potential for selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, anti-psychotics and other seizure threshold lowering medicinal products (such as bupropion, mirtazapine, tetra-hydrocannabinol) to cause convulsions.
Concomitant therapeutic use of **MAKLODOL 50 mg** tablets and serotonergic medicines such as selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors (see **Section 4.3**), tricyclic antidepressants and mirtazapine may cause serotonin toxicity. The Serotonin syndrome is likely when one of the following is observed:
- Spontaneous clonus;
- Inducible or ocular clonus with agitation or diaphoresis;
- Tremor and hyperreflexia;
- Hypertonia and body temperature > 38 °C and inducible or ocular clonus.

Withdrawal of the serotonergic medicines usually brings about a rapid improvement.
Treatment depends on the type and severity of the symptoms.
Caution should be exercised during concomitant treatment with **MAKLODOL 50 mg** tablets and warfarin–like medicines due to reports of increased International Normalised Ratio (INR) with major bleeding and ecchymoses in some patients.
The inhibition of one or both types of isoenzymes CYP3A4 and CYP2D6 involved in the biotransformation of tramadol may affect the plasma concentration of tramadol or its active metabolite.
Other active substances known to inhibit CYP3A4, such as ketoconazole and erythromycin, might inhibit the metabolism of tramadol (N-demethylation) probably also the metabolism of the active O-demethylated metabolite. The clinical importance of such an interaction has not been studied (see **Section 5.1**).
The antiemetic 5-HT3 antagonist ondansetron increases the requirement of **MAKLODOL 50 mg** tablets in patients with postoperative pain. **MAKLODOL 50 mg** tablets may decrease the antiemetic efficacy of ondansetron.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety during pregnancy and lactation has not been established. Therefore, **MAKLODOL 50 mg** tablets should not be used in pregnant women. **MAKLODOL 50 mg** crosses the placenta. Animal studies with **MAKLODOL 50 mg** revealed effects on organ development, ossification and neonatal mortality. The administration of **MAKLODOL 50 mg** tablets during pregnancy may lead to habituation in the unborn child. The child may experience withdrawal symptoms after birth (see **Section 4.3**).

Breastfeeding
MAKLODOL 50 mg passes into breastmilk. Mothers on **MAKLODOL 50 mg** tablets should not breastfeed their infants.

4.7 Effects on ability to drive and use machines
MAKLODOL 50 mg tablets may affect reactions to the extent that driving ability and the ability to operate machinery may be impaired. This applies particularly in conjunction with other psychotropic medicines including alcohol.

4.8 Undesirable effects
Table 1: The following adverse reactions have been reported in association with **MAKLODOL 50 mg** tablets:

System Organ Class	Frequency	Undesirable effects
Immune system disorders:	Less frequent	Allergic reactions (e.g. dyspnoea, bronchospasm,wheezing, angioedema) and anaphylaxis.
Metabolism and nutrition disorders:	Less frequent	Changes in appetite.
Psychiatric disorders:	Less frequent	Hallucinations, confusional states, sleep disturbances, delirium, anxiety and nightmares. Changes in mood (euphoria, dysphoria), decreased activity, restlessness and changes in cognitive and sensorial capacity (such as decision behaviour, perception disorders).
Nervous system disorders:	Frequent	Dizziness headaches, somnolence
	Less frequent	Speech disorders, paraesthesia, tremor, convulsions, involuntary muscle contractions, abnormal coordination, syncope.
Eye disorders:	Less frequent	Miosis, mydriasis, blurred vision.
Cardiac disorders:	Less frequent	Dysrhythmias, palpitation, tachycardia, bradycardia.
Vascular disorders:	Less frequent	Postural hypotension, cardiovascular collapse. increase in blood pressure.
Respiratory, thoracic and mediastinal disorders:	Less frequent	Respiratory depression, dyspnoea, bronchospasm.
Gastrointestinal disorders:	Frequent	Nausea, vomiting, constipation, dry mouth.
	Less frequent	Retching, gastrointestinal discomfort, acute pancreatitis, abdominal pain
Hepatobiliary disorders:	Less frequent	Increase in transaminases (ALT and AST) is expected.
Skin and subcutaneous tissue disorders:	Frequent	Hyperhidrosis
	Less frequent	Dermal reactions (e.g. pruritus, rash, urticaria).
Musculoskeletal and connective tissue disorders:	Less frequent	Muscular weakness.
Renal and urinary disorders:	Less frequent	Micturition disorders (dysuria and urinary retention).
General disorders and administration site conditions:	Frequent	Fatigue.

Post marketing experience
Nervous system complaints
Speech disorders.
Eye disorders
Mydriasis.
Skin and subcutaneous tissue disorders
Stevens Johnson Syndrome,
Toxic Epidermal Necrolysis.
Gastrointestinal disorders:
Increased risk of abdominal pain, including pancreatitis has been reported. Frequency: rare

Cases of hyponatraemia and/or SIADH have been reported in patients taking tramadol, usually in patients with predisposing risk factors, such as the elderly or those using concomitant medications that may cause hyponatraemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Symptoms
Following an overdose with **MAKLODOL 50 mg** tablets, symptoms similar to those of other centrally acting analgesics (opioids) are to be expected. These include in particular constriction of the pupil of the eye, vomiting, cardiovascular collapse, consciousness disorders, coma, convulsions, respiratory depression and respiratory arrest.

Treatment
The general emergency measures apply. Keep open the respiratory tract, maintain respiration and circulation depending on the symptoms. Suitable measures should be taken to avoid aspiration dangers.
Respiratory depression can be antagonised with a pure opiate antagonist (naloxone).
Convulsions should be treated with intravenous diazepam.
In cases of intoxication with oral formulations, gastrointestinal decontamination with activated charcoal is only recommended within 2 hours after **MAKLODOL 50 mg** tablets intake.
Gastrointestinal decontamination at a later time point may be useful in case of intoxication with exceptionally large quantities.
Tramadol is minimally eliminated from the serum by haemodialysis or haemofiltration. Treatment of acute intoxication with **MAKLODOL 50 mg** tablets with haemodialysis or haemofiltration alone is therefore not suitable for detoxification.

5. PHARMACOLOGICAL PROPERTIES

Pharmaceutical groups:
A.2.9. Other analgesics
ATC code: N02AX02.

5.1 Pharmacodynamic properties
Tramadol hydrochloride is a centrally acting analgesic with binding to specific opioid receptors. It is a non-selective, agonist at mu (μ), delta (δ) and kappa (k) opioid receptors with a higher affinity for the μ receptor. Other mechanisms, which contribute to its analgesic effect, are inhibition of neuronal re-uptake of noradrenaline as well as the enhancement of serotonin release. The relationship between serum concentrations and the analgesic effect is dose-dependent, but varies considerably. Patients devoid of CYP2D6 may need higher doses of tramadol, to achieve adequate analgesia.

5.2 Pharmacokinetic properties
Absorption
After oral administration of **MAKLODOL 50 mg** tablets, tramadol hydrochloride is absorbed with an absorption half-life ($t½_{ka}$) of 0, 38 ± 0, 18 hours.
Distribution
The mean systemic bioavailability is 68 %, independent of food intake.
Tramadol has a linear pharmacokinetic profile within the therapeutic dosage range.
Biotransformation and Elimination
The elimination half-life is 5 to 7 hours. Tramadol is mainly metabolised in the liver (90 %).
Tramadol hydrochloride and its metabolites are almost completely excreted by the renal route (95 %). Biliary excretion of these components is quantitatively insignificant and is therefore subject to hepatic metabolism and renal elimination.
The terminal half-life ($t½_{\beta}$) is prolonged in impaired hepatic or renal function. In patients with liver cirrhosis, the mean $t½_{\beta}$ of tramadol was 13,3 ± 4,9 h, $t½_{\beta}$ /M1 18,5 ± 9,4 h, in patients with renal insufficiency (creatinine clearance ≤ 5 ml/min) the values were 11,0 ± 3,2 h (tramadol) and 16,9 ± 3,0 h (M1) respectively.
The inhibition of one or both types of isoenzymes CYP3A4 and CYP2D6 involved in the biotransformation of tramadol may affect the plasma concentration of tramadol or its active metabolite. Tramadol hydrochloride crosses the blood-brain and placental barrier. Small amounts are excreted in breast milk unchanged or as the metabolite M1.

5.3 Preclinical safety data
Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
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).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
48 months from the manufacturing date.

6.4 Special precautions for storage
Store at or below 25 °C.
Keep the HDPE containers closed.
Keep the blister in the carton until required for use.
Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
Container Pack
Tablets are packed in a round white opaque plastic container (HDPE) and are closed with a white closure, packed in an outer carton. Pack sizes include 100 tablets.
Blister Pack
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. Pack sizes include 20 and 100 tablets.
Not all packs and pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
Office block 1, Bassonia Estate Office Park (East), 1 Cussonia Drive,
Bassonia Rock, Ext. 12, Alberton, South Africa.

8. REGISTRATION NUMBER(S)

MAKLODOL 50 mg: 52/2.9/0750.749

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15 March 2023

10. DATE OF REVISION OF THE TEXT

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

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

1. What MAKLODOL 50 mg is and what it is used for

Tramadol, the active substance in **MAKLODOL 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 MAKLODOL 50 mg

Do not take or give MAKLODOL 50 mg:
- if you are allergic to tramadol or any of the other ingredients of **MAKLODOL 50 mg** tablets. (Refer to **WHAT MAKLODOL 50 mg CONTAINS**, above);
- 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 **MAKLODOL 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 **MAKLODOL 50 mg**:
Some people will need special care from their doctors when they are taking **MAKLODOL 50 mg**. Make sure that your doctor knows before you start taking **MAKLODOL 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 **MAKLODOL 50 mg** tablets is exceeded;
- if you suffer from a liver or kidney disease.
- If you have a family history of substance abuse or mental health issues.
- 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 **MAKLODOL 50 mg**, consult with your doctor immediately. **MAKLODOL 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. **MAKLODOL 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.
- **MAKLODOL 50 mg** contains sugar (lactose monohydrate). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **MAKLODOL 50 mg**.

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

Use in children
MAKLODOL 50 mg tablets are not suitable for children under the age of 12 years.

Other medicines and MAKLODOL 50 mg
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
The following information is particularly important:
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

MAKLODOL 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 **MAKLODOL 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 **MAKLODOL 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 **MAKLODOL 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 **MAKLODOL 50 mg** tablets at the same time. Your doctor will tell you whether **MAKLODOL 50 mg** tablets are suitable for you.
- If you are taking certain antidepressants such as Selective Serotonin Reuptake Inhibitors or MAO inhibitors. **MAKLODOL 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 **MAKLODOL 50 mg** tablets. The effect of warfarin on blood clotting may be increased and bleeding may occur.

MAKLODOL 50 mg with food and drink
Do not drink alcohol during treatment with **MAKLODOL 50 mg** tablets as the effects of **MAKLODOL 50 mg** and alcohol may intensify each others effects. Food does not influence the effect of **MAKLODOL 50 mg** tablets.

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

Driving and using machines
MAKLODOL 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 **MAKLODOL 50 mg** tablets affect you.
It is not always possible to predict to what extent **MAKLODOL 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 **MAKLODOL 50 mg** affects them.

3. How to take MAKLODOL 50 mg

Do not share medicines prescribed for you with any other person.
Always take or give **MAKLODOL 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 **MAKLODOL 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 **MAKLODOL 50 mg** tablets daily.
Tablets are to be taken whole, not divided or chewed, with sufficient liquid, with or without food.

The usual dose is:
Adults and patients over 18 years of age:
Moderate pain: Take an initial dose of 50 mg tramadol (1 **MAKLODOL 50 mg** tablet), followed by 50 mg or 100 mg every 4 to 6 hours.

UNICORN
MAKLODOL 50 mg
(film-coated tablet)
PM04341091

Back Side

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 **MAKLODOL 50 mg** tablets for longer than is absolutely necessary.

Children (below the age of 12):
MAKLODOL 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 **MAKLODOL 50 mg** tablets may be delayed. Your doctor may direct you to prolong your dosage intervals.

If you take more MAKLODOL 50 mg than you should
- Seek emergency medical attention if you think you have taken too much of **MAKLODOL 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 MAKLODOL 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.

If you stop taking MAKLODOL 50 mg
If treatment with **MAKLODOL 50 mg** is stopped earlier than your doctor has prescribed, your disease may become worse. Always take **MAKLODOL 50 mg** for as long as your doctor has prescribed.
If you interrupt or finish treatment with **MAKLODOL 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 **MAKLODOL 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 **MAKLODOL 50 mg** tablets, consult your doctor.

4. Possible side effects

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

If any of the following happens, stop taking MAKLODOL 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 **MAKLODOL 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:
- 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;
- 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.

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 **MAKLODOL 50 mg.**

5. How to store MAKLODOL 50 mg

Store at or below 25 ℃ (room temperature).
Keep the HDPE container closed.
Keep the blister in the carton until required for use.
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 MAKLODOL 50 mg contains
Each tablet 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 MAKLODOL 50 mg looks like and contents of the pack
MAKLODOL 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 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
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

MARKETED BY :
United Pharma Marketing (Pty) Ltd.

This leaflet was last revised in
15 March 2023

Registration number
MAKLODOL 50 mg : 52/2.9/0750.749

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S5

MAKLODOL 50 mg filmbedekte tablet
50 mg Tramadolhidrochloried
Bevat suiker: (125,30 mg laktosemonohidraat)

Lees hierdie inligtingstuk sorgvuldig voordat jy MAKLODOL 50 mg begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter of apteker, indien jy verdere vrae het.
- **MAKLODOL 50 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk?
1. Wat **MAKLODOL 50 mg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **MAKLODOL 50 mg** neem
3. Hoe om **MAKLODOL 50 mg** te gebruik
4. Moontlike newe-effekte
5. Hoe om **MAKLODOL 50 mg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat MAKLODOL 50 mg is en waarvoor dit gebruik word

Tramadol, die aktiewe bestanddeel in **MAKLODOL 50 mg** tablette, is 'n pynstiller wat aan die klas van die opioïede behoort wat op die sentrale senuweestelsel inwerk. Dit word gebruik vir die hantering van matige tot matige-erge pyn.

2. Wat jy behoort te weet voordat jy MAKLODOL 50 mg neem of gee

Moet nie MAKLODOL 50 mg neem of gee nie:
- indien jy allergies is vir tramadol of enige van die ander bestanddele van **MAKLODOL 50 mg** tablette. (Verwys na **WAT MAKLODOL 50 mg BEVAT**, hierbo);
- in akute vergiftiging met alkohol, slaappille, pynstillers of ander psigotropiese middels (medisyne wat gemoedstoestand en emosies beïnvloed);
- indien jy MAO-inhibeerders neem (sekere medisyne wat vir depressie gebruik word) of dit in die laaste 14 dae voor behandeling met **MAKLODOL 50 mg** tablette geneem het;
- indien jy epilepsie het;
- indien 'n plaasvervanger in dwelm onttrekking;
- indien jy swanger is of jou baba borsvoed (sien **Swangerskap en Borsvoeding**).

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **MAKLODOL 50 mg**:
Sommige mense sal spesiale sorg van hul dokters benodig wanneer hulle **MAKLODOL 50 mg** neem.
Maak seker dat jou dokter weet voordat jy **MAKLODOL 50 mg** begin neem:
- indien jy dink dat jy verslaaf is aan ander pynstillers (opioïede);
- indien jy aan bewussynsversteurings ly (as jy floutes het of jy voel dat jy gaan flou word);
- indien jy in 'n toestand van skok is (koue sweet kan 'n teken daarvan wees);
- indien jy aan verhoogde druk in die brein ly (moontlik na 'n kopbesering of breinsiekte);
- indien jy sukkel om asem te haal;
- indien jy 'n neiging tot epilepsie of aanvalle het omdat die risiko van 'n aanval kan toeneem; veral wanneer die boonste doserings limiet (400 mg) van **MAKLODOL 50 mg** tablette oorskry word;
- indien jy aan 'n lewer- of niersiekte ly.
- As jy 'n familiegeskiedenis van dwelmmisbruik of geestesgesondheidsprobleme het.
- Tramadol werk deur omgeskakel (gemetaboliseer) te word in sy aktiewe komponent. Wanneer jy Tramadol vinniger en vollediger omskakel (metaboliseer) na hierdie aktiewe komponent as ander pasiënte, staan jy bekend as 'n ultra-vinnige metaboliseerder. Indien jy 'n ultra-vinnige metaboliseerder is, is jy meer geneig om ernstige newe-effekte te hê, soos probleme met asemhaling, met stadige of vlak asemhaling. Indien jy hierdie tipe newe-effekte ervaar, hou op om hierdie medisyne te neem en raadpleeg onmiddellik jou dokter.
- Jy kan lae vlakke van natrium in die bloed ondervind (hiponatremie) terwyl jy hierdie medisyne neem. Simptome van lae bloednatrium kan naarheid en braking, hoofpyne, verwarde gevoel, baie moeë gevoel, rustelose gevoel, prikkelbare gevoel, spierswakheid, -spasmas of -krampe en aanvalle insluit. Bejaarde pasiënte en pasiënte wat ander medisyne gebruik wat natrium in die bloed verlaag, loop die grootste risiko vir hierdie newe-effek. Indien jy enige van hierdie simptome kry terwyl jy **MAKLODOL 50 mg** neem, raadpleeg onmiddellik jou dokter. **MAKLODOL 50 mg** tablette kan in sommige mense tot sielkundige en fisiese afhanklikheid of verslawing lei, veral met langtermyn gebruik. Die dosis wat nodig is om die gewenste effek te bereik, kan met tyd verhoog. **MAKLODOL 50 mg** tablette moet met omsigtigheid gebruik word, en slegs vir kort periodes onder streng mediese toesig, in pasiënte wat aan ander opioïed pynstillers verslaaf is.
- **MAKLODOL 50 mg** bevat suiker (laktosemonohidraat). Indien jou dokter vir jou gesê het dat jy onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy **MAKLODOL 50 mg** gebruik.

Stel asseblief ook jou dokter in kennis indien enige van hierdie probleme voorkom gedurende behandeling met **MAKLODOL 50 mg** tablette, of indien dit op jou van toepassing was in die verlede.

Gebruik in kinders
MAKLODOL 50 mg tablette is nie geskik vir kinders jonger as 12 jaar oud nie.

Ander medisyne en MAKLODOL 50 mg
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Die volgende inligting is veral belangrik:
Stel asseblief jou dokter of apteker in kennis indien jy enige ander medisyne neem of onlangs geneem het, selfs dié wat nie voorgeskryf is nie.
- **MAKLODOL 50 mg** tablette moet nie saam met Monoamienoksidase (MAO) inhibeerders (sekere medisyne vir die behandeling van depressie), of binne 2 weke na die staking van behandeling daarmee, gebruik word nie.
- Die pynstillende effek van **MAKLODOL 50 mg** tablette kan verminder word en die tydsduur van werking kan verkort word indien jy medisyne neem wat die volgende bevat:
  - Karbamasepien (vir epileptiese aanvalle);
  - Ondansetron (voorkom naarheid).

Jou dokter sal vir jou sê of jy **MAKLODOL 50 mg** tablette moet gebruik, en teen watter dosering.
Die risiko van newe-effekte neem toe,
- Indien jy kalmeermiddels, slaappille, ander pynstillers soos morfien en kodeïen (ook as hoesmedisyne) en alkohol neem terwyl jy **MAKLODOL** 50 **mg** tablette gebruik. Jy kan moontlik meer lomerig voel of voel dat jy moontlik wil flou val. Wanneer dit gebeur, vertel jou verpleegkundige of dokter.
- Indien jy medisyne neem wat aanvalle kan veroorsaak soos sekere antidepressante of antipsigotika. Die risiko om 'n aanval te kry kan toeneem indien jy **MAKLODOL 50 mg** tablette op dieselfde tyd neem. Jou dokter sal jou vertel of **MAKLODOL 50 mg** tablette vir jou geskik is. Indien jy sekere antidepressante soos Selektiewe Serotonien Heropname Inhibeerders of MAO-inhibeerders gebruik. **MAKLODOL 50 mg** tablette kan met hierdie medisyne in wisselwerking tree en jy kan simptome soos onwillekeurige, ritmiese sametrekkings van spiere ervaar, insluitend spiere wat beweging van die oog beheer, opgewondenheid, oormatige sweet, bewing, oordrywing van reflekse, verhoogde spierspanning, liggaamstemperatuur bo 38 °C. Indien jy warfarien saam met **MAKLODOL 50 mg** tablette neem. Die effek van warfarien op bloedstolling kan verhoog word en bloeding kan voorkom**.**

MAKLODOL 50 mg met voedsel en drank
Moet nie tydens behandeling met **MAKLODOL 50 mg** tablette alkohol drink nie, aangesien **MAKLODOL 50 mg** en alkohol mekaar se effekte kan versterk. Voedsel beïnvloed nie die effek van **MAKLODOL 50 mg** tablette nie.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, dink dat jy moontlik swanger is of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy **MAKLODOL 50 mg** tablette neem.
Indien **MAKLODOL 50 mg** tablette op 'n langtermynbasis gedurende swangerskap gebruik word, sal dit tot skade (onttrekkingsimptome) in pasgeborenes lei.
Jy moet nie **MAKLODOL 50 mg** tablette neem indien jy swanger is nie.
Die gebruik van **MAKLODOL 50 mg** tablette word nie tydens borsvoeding aanbeveel nie. **MAKLODOL 50 mg** word in borsmelk uitgeskei. Indien jy **MAKLODOL 50 mg** tablette neem, moet jy nie jou baba borsvoed nie.

Bestuur en gebruik van masjiene
MAKLODOL 50 mg tablette kan lomerigheid, duiseligheid en dowwe visie veroorsaak en kan dus jou reaksies inkort. Moet nie 'n motor of ander voertuig bestuur nie, moet nie elektriese gereedskap gebruik of masjinerie beheer totdat jy seker is hoe **MAKLODOL 50 mg** tablette jou beïnvloed nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **MAKLODOL 50 mg** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie in bogenoemde aktiwiteite betrokke raak nie, totdat hulle bewus is van die mate waartoe **MAKLODOL 50 mg** hulle affekteer.

3. Hoe om MAKLODOL 50 mg te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem of gee altyd **MAKLODOL 50 mg** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is.
Indien jy onder die indruk is dat die effek van **MAKLODOL 50 mg** te sterk of te swak is, praat met jou dokter of apteker.
Vertel altyd jou gesondheidsorgwerker as jy enige ander medisyne neem (Dit sluit komplementêre of tradisionele medisyne in).
Die dosering moet volgens die intensiteit van jou pyn en jou individuele pynsensitiwiteit aangepas word. Die laagste pynstillende dosis moet geneem word.
Moet nie meer as 400 mg **MAKLODOL 50 mg** tablette per dag neem nie.
Tablette moet heel geneem word, nie verdeel of gekou nie, met voldoende vloeistof, met of sonder voedsel.

Die gewone dosis is:
Volwassenes en pasiënte ouer as 18 jaar oud:
Matige pyn: Neem 'n aanvanklike dosis van 50 mg tramadol (1 **MAKLODOL 50 mg** tablet), gevolg deur 50 mg of 100 mg elke 4 tot 6 ure.
Erge pyn: Neem 'n aanvanklike dosis van 100 mg gevolg deur 50 mg of 100 mg elke 4 tot 6 ure.
Jy moet nie **MAKLODOL 50 mg** tablette langer gebruik as wat absoluut nodig is nie.

Kinders (jonger as 12 jaar oud):
MAKLODOL 50 mg tablette is nie geskik vir kinders jonger as 12 jarige ouderdom nie.

Bejaarde pasiënte (ouer as 75 jaar oud):
'n Dosisvermindering en/of verlenging van die interval tussen doserings word aanbeveel.
Lewer- of niersiekte (inkorting)/dialise pasiënte.
Indien jy aan lewer- en/of nierinkorting ly, kan die uitskeiding van **MAKLODOL 50 mg** tablette vertraag word. Jou dokter kan jou beveel om jou doserings intervalle te verleng.

Indien jy meer MAKLODOL 50 mg geneem het as wat jy behoort te neem
- Soek nood mediese hulp indien jy vermoed dat jy te veel **MAKLODOL 50 mg** geneem het.

Indien jy per abuis 'n addisionele dosis geneem het, sal dit oor die algemeen geen negatiewe uitwerking hê nie. Jy moet jou volgende dosis neem soos jou dokter dit vir jou voorgeskryf het.
Na die inname van baie hoë doserings, klein of wye pupille, braking, val in bloeddruk, vinnige hartklop, flou gevoel, afname in bewussynsvlak tot op koma (diep bewusteloosheid), epileptiese aanvalle en moeilike asemhaling tot ophou van asemhaling kan voorkom.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om MAKLODOL 50 mg te neem
Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, en gaan dan voort soos voorheen. Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om MAKLODOL 50 mg te gebruik
Indien behandeling met **MAKLODOL 50 mg** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou siekte vererger. Neem altyd **MAKLODOL 50 mg** vir so lank as wat jou dokter dit voorgeskryf het.
Wanneer jy behandeling met **MAKLODOL 50 mg** tablette te gou onderbreek of klaarmaak, kan jou pyn terugkeer. Indien jy die behandeling wil staak weens ongewenste effekte, vertel asseblief vir jou dokter.
Indien jy **MAKLODOL 50 mg** tablette vir 'n geruime tyd geneem het, kan jy onwel voel indien jy die behandeling skielik staak. Jy kan rusteloos, angstig, senuweeagtig of bewerig voel. Jy kan hiperaktief wees, sukkel om te slaap en maag- of dermafwykings hê. Jy kan paniekaanvalle, hallusinasies, ongewone persepsies soos jeuk, tinteling en gevoelloosheid, en gesuis in ore (tinnitus) kry.
Verdere ongewone simptome van die sentrale senuweestelsel (SSS), d.w.s. verwarring, delusie, verandering in hoe jy jou eie persoonlikheid sien (waarneem) (depersonalisering), en verandering in hoe jy die werklikheid sien (waarneem) (derealisering) en delusie van vervolging (vervolgingswaansin) is aangemeld. Wanneer jy enige van hierdie effekte ervaar nadat jy opgehou het om **MAKLODOL 50 mg** tablette te neem, raadpleeg jou dokter.

4. Moontlike newe-effekte

MAKLODOL 50 mg kan newe-effekte hê.
Nie al die newe-effkte wat vir **MAKLODOL 50 mg** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **MAKLODOL 50 mg** gebruik, kontak asseblief jou gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om MAKLODOL 50 mg te gebruik en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- geswelde gesig, tong en/of keel, en/of probleme met sluk of asemhaling of asemgefluit;
- uitslag, swelling of jeuk van die vel;
- skok (skielike sirkulasieversaking).

Hierdie is almal baie ernstige newe-effkte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op **MAKLODOL 50 mg** gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk of ervaar:
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy agterkom dat jou hart vinniger klop;
- bonsing (dit kan veral voorkom wanneer jy onder spanning is, 'n stadige hartklop het, 'n toename in bloeddruk of posisie verander van 'n regop posisie na sit of lê);
- voel flou;
- verlies van bewussyn;
- stadige asemhaling;
- kort van asem;
- aanvalle (stuiptrekkings);
- met moeite of pyn urineer, minder uriene passeer as wat vir jou normaal is.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte
- duiseligheid
- hoofpyne
- lomerigheid
- naarheid (voel siek, drang om te braak);
- braking;
- hardlywigheid;
- droë mond;
- sweet meer as wat vir jou normaal is;
- moegheid.

Minder gereelde newe-effekte
- abnormale sensasies byvoorbeeld as jy jeuk, tinteling of gevoelloosheid ervaar;
- bewe;
- spiertrekkings;
- ongekoördineerde beweging;
- veranderinge in eetlus;
- hallusinasie;
- verwarde toestand;
- slaapversteurings;
- ylhoofdigheid;
- angs;
- nagmerries;
- veranderinge in bui byvoorbeeld jy kan gelukkig of geïrriteerd voel;
- verminderde aktiwiteit;
- rusteloosheid;
- veranderinge in die manier waarop jy dinge sien of beskou;
- dowwe visie;
- vernouing van die pupil;
- maagprobleme (bv. gevoel van druk in die maag, opgeblasenheid);
- diaree (gereelde of los waterige stoelgange);
- swak spiere;
- verhoogde lewerensiem;
- akute pankreatitis;
- maagpyn.

Die volgende newe-effekte is gerapporteer tydens na-bemarking waarneming
- spraakversteuring;
- oormatige verwyding van jou pupille;
- Stevens Johnson se sindroom - 'n seldsame, ernstige **afwyking** van die vel en slymvliese. Dit begin met griepagtige simptome, gevolg deur 'n pynlike uitslag wat versprei en blase vorm.
- Lae natriumvlakke in die bloed en/of onvanpaste antidiuretiese hormoonafskeiding (SIADH).
- Verhoogde risiko van abdominale pyn, insluitend akute pankreatitis. Frekwensie: skaars

Indien enige van die newe-effekte ernstig word, of as jy een van die bogenoemde ernstige newe-effekte ervaar, kontak die naaste dokter onmiddellik. Lig asseblief jou dokter of apteker in indien jy enige newe-effek ervaar wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies:https://www.sahpra.org.za/Publications/Index/8

Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **MAKLODOL 50 mg**.

5. Hoe om MAKLODOL 50 mg te bewaar

Bewaar by of benede 25°C (kamertemperatuur).
Hou die HDPE houer dig gesluit.
Hou die stulpverpakking in die karton tot benodig vir gebruik.
Beskerm teen lig en vog.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Stoor in die oorspronklike verpakking/houer.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat MAKLODOL 50 mg bevat
Elke tablette bevat 50 mg tramadolhidrochloried.
Bevat laktose.
Die ander bestanddele is: Kolloïdale silikondioksied, hipromellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, natriumstysellglikolaat en bedekkings agent bevat hipromellose 6 cPs, poliëtileenglikool 400, polisorbaat 80 en titaniumdioksied.
Bevat suiker (laktose).

Hoe MAKLODOL 50 mg lyk en inhoud van die pak
MAKLODOL 50 mg:
Wit tot naaswit, kapsuulvormige, bikonvekse, filmbedekte tablette met "ML 4" aan die een kant gegraveer en glad aan die ander kant.

HDPE houer verpakking 100's:
Tablette word in 'n ronde wit ondeursigtige plastiekhouer (HDPE) verpak en is gesluit met 'n wit sluiting, verpak in 'n buitenste karton. Verpakkings groottes sluit 100 tablette in.
Stulpverpakkings 20's en 100's:
Helder, deursigtige PVC 250 µm as die vormingsmateriaal en silwerkleurige, gewone 25 µm aluminiumfoelie/ 6 - 8 gsm HSL in 'n voorafgedrukte buitenste karton.
Nie alle verpakkings en verpakkings grootte word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos), Cussonia Weg 1,
Bassonia Rock, Uitbr. 12, Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
15 Maart 2023

Registrasienommer
MAKLODOL 50 mg: 52/2.9/0750.749

Marketed by:
United Pharma Marketing (Pty) Ltd
2512B256

400 mm

435 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Change in shelf life, marketing holder, CR closure removal and warnings updation as per SAHPRA recommendation.

1. Product: MAKLODOL 50 mg (Tramadol Hydrochloride Tablets 50 mg)						
2. Country: South Africa (UNICORN)			**3. Packaging component: Patient Information Leaflet**			
4. No. of Colours: 1 Colour			**5. Pantone Shade No.: Black**			
6. Specification: 40 gsm bible paper						
7. Machine Layout No.: NA			**8. Dimensions: 435 (L) x 400(W) mm**			
9. Design / Style: Booklet			**10. Item code No.: PM04341091**			
11. Artwork has been made: Actual Size			**12. Pharma code No.: 40772 mini**			
13. Barcode/NDC no: NA			**14. Supersedes Item code No: NA**			
15. Revision no: 00			**16. A/W File name: E:\SOUTH AFRICA\South Africa\Tramadol\UNICORN\02\Tramadol 50 mg PI & PIL - PM04341091.cdr**			
Approved By:			**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**RAD**	**QC**	**PRODN**	**QA**	**UNICORN**
	19/01/2026					APPROVED By Carine Page at 2:15 pm, Jan 19, 2026

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Unicorn	PM04133001	29/05/2023	28/07/2023
2) Change in shelf life, marketing holder, CR closure removal and warnings updation as per SAHPRA recommendation.	PM04341091		