SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of the medicinal Product

Name of the Medicinal Product

Tramadol Capsule 100 mg

2. Qualitative and Quantitative Composition

Tramadol Hydrochloride.....100 mg
Excipients q.s.

3. Pharmaceutical Form

Green /Green , size `2' hard gelatin capsule containing white free flowing powder.

4. Clinical Particulars

4.1 Therapeutic Indications

The treatment of moderate to severe pain.

4.2 Posology and Method of Administration

The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient. The lowest effective dose for analgesia should generally be selected.

Adults and adolescents aged 12 years and over
100-200 mg tramadol hydrochloride twice daily (corresponding to 200 – 400 mg of tramadol hydrochloride/day), morning and evening administration recommended.
The smallest effective analgesic dose should always be used. Daily doses of 400 mg of active substance must not be exceeded, unless exceptional medical reasons require so. A minimum interval of 8 hours must be respected between administrations.
Paediatric population
Tramadol Capsule 100 mg is not suitable for use in children below 25 kg body weight which in general does not allow for individualized dosage in children below 12 years of age.
Consequently, a more suitable form of administration should be used.
Geriatric patients
A dose adjustment is not usually necessary in patients up to 75 years without clinically manifest hepatic or renal insufficiency. In elderly patients over 75 years elimination may be prolonged. Therefore, if necessary the dosage interval is to be extended according to the patient's requirements.
Renal insufficiency/dialysis and hepatic impairment TRAMADOL CAPSULE 100 MG
In patients with renal and/or hepatic insufficiency the elimination of tramadol is delayed. In these patient's prolongation of the dosage intervals should be carefully considered according to the patient's requirements. In cases of severe renal and/or severe hepatic insufficiency MAXITRAM SR prolonged-release hard capsules are not recommended.
Oral: route of administration

4.3 Contraindications

The prolonged-release capsule, hard, must be swallowed whole with sufficient liquid, irrespective of mealtimes.

4.4 Special Warnings and Special Precautions for Use

Tramadol capsules are contraindicated:
• in hypersensitivity to the active substance.
• in acute intoxication with alcohol, hypnotics, analgesics, opioids, or other psychotropic medicinal products).
• in patients who are receiving MAO inhibitors or who have taken them within the last 14 days.
• in patients with epilepsy not adequately controlled by treatment.
• during breastfeeding, if long term treatment, i.e. more than 2 to 3 days, is necessary.
• for use in narcotic withdrawal treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Tramadol may only be used with particular caution in opioid-dependent patients, patients with head injury, shock, a reduced level of consciousness of uncertain origin, disorders of the respiratory centre or function, increased intracranial pressure.
In patients sensitive to opiates the product should only be used with caution.
Concomitant use of Tramadol and sedating medicinal products such as benzodiazepines or related substances, may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedating medicinal products should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Tramadol concomitantly with sedating medicinal products, the lowest effective dose of tramadol should be used, and the duration of concomitant treatment should be as short as possible.
The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms.
Convulsions have been reported in patients receiving tramadol at the recommended dose levels. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg). In addition, tramadol may increase the seizure risk in patients taking other medicinal products that lowers the seizure threshold (see section 4.5). Patients with epilepsy or those susceptible to seizures should be only treated with tramadol if there are compelling circumstances.
Care should be taken when treating patients with respiratory depression, or if concomitant CNS depressant drugs are being administered, or if the recommended dosage is significantly exceeded as the possibility of respiratory depression cannot be excluded in these situations.

Sleep-related breathing disorders
Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.
Drug dependence, tolerance and potential for abuse
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).
Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.
A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained

on-line, and past and present medical and psychiatric conditions.
Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of pain control as initially experienced. Patients may also supplement their treatment with additional pain relievers. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.
Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.
Patients should be closely monitored for signs of misuse, abuse, or addiction. The clinical need for analgesic treatment should be reviewed regularly.
Drug withdrawal syndrome
Prior to starting treatment with any opioids, a discussion should be held with patients to put in place a withdrawal strategy for ending treatment with Tramadol.
Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months. The opioid drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.
If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.
Hyperalgesia
Hyperalgesia may be diagnosed if the patient on long-term opioid therapy presents with increased pain. This might be qualitatively and anatomically distinct from pain related to disease progression or to breakthrough pain resulting from development of opioid tolerance. TRAMADOL CAPSULE 100 MG
Pain associated with hyperalgesia tends to be more diffuse than the pre-existing pain and less defined in quality. Symptoms of hyperalgesia may resolve with a reduction of opioid dose. Tramadol is not suitable as a substitute in opioid-dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms.
CYP2D6 metabolism
Tramadol is metabolised by the liver enzyme CYP2D6. If a patient has a deficiency or is completely lacking this enzyme an adequate analgesic effect may not be obtained. Estimates indicate that up to 7% of the Caucasian population may have this deficiency. However, if the patient is an ultra-rapid metaboliser there is a risk of developing <side effects> of opioid toxicity even at commonly prescribed doses.

4.6 Fertility, Pregnancy and Lactation

Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.
If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
Tramadol - administered before or during birth - does not affect uterine contractility. Administration during labour may depress respiration in the neonate and an antidote for the child should be readily available.

Breast-feeding

Administration to nursing women is not recommended as Tramadol may be secreted in breast milk and may cause respiratory depression in the infant. Alternatively, breast-feeding should be discontinued during treatment with tramadol. Discontinuation of breast-feeding is generally not necessary following a single dose of tramadol.
Approximately 0.1 % of the maternal dose of tramadol is excreted in breast milk. In the immediate post-partum period, for maternal oral daily dosage up to 400 mg, this corresponds
to a mean amount of tramadol ingested by breast-fed infants of 3% of the maternal weightadjusted dosage. Fertility
Post marketing surveillance does not suggest an effect of tramadol on fertility. Animal studies did not show an effect of tramadol on fertility.

4.7 Effects on ability To Drive and use Machines

Non reported

4.8 Undesirable Effects

The most adverse reactions are nausea and dizziness.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties Pharmacotherapeutic group: Analgesics, other opioids. ATC Code: N02AX02
Mechanism of action
Tramadol is a centrally-acting opioid analgesic. It is a non-selective pure agonist at μ, δ, and κ opioid receptors with a higher affinity at the μ receptors. Other mechanisms that contribute to its analgesic effect are inhibition of neuronal re-uptake of noradrenaline as well as increased serotonin release.
Clinical efficacy and safety
Tramadol has an antitussive effect. In contrast to morphine, tramadol in analgesic doses has no respiratory depression effect over a wide range and no effect on gastrointestinal motility. It has only a slight effect on the cardiovascular system.
Tramadol potency is given as 1/10 to 1/6 of that for morphine. Paediatric population
Effects of enteral and parenteral administration of tramadol have been investigated in clinical trials involving more than 2000 paediatric patients ranging in age from neonate to 17 years of age. The indications for pain treatment studied in those trials included pain after surgery (mainly abdominal), after surgical tooth extractions, due to fractures, burns and traumas as well as other painful conditions likely to require analgesic treatment for at least 7 days.
At single doses of up to 2 mg/kg or multiple doses of up to 8 mg/kg per day (to a maximum of 400 mg per day) efficacy of tramadol was found to be superior to placebo, and superior or equal to paracetamol, nalbuphine, pethidine or low dose morphine. The conducted trials confirmed the efficacy of tramadol. The safety profile of tramadol was similar in adult and paediatric

patients older than 1 year.

5.2 Pharmacokinetic Properties

Absorption

Following oral use tramadol absorption is greater than 90%. Absolute average bioavailability is 70%, irrespective of concurrent food intake. The difference between available absorbed and unmetabolized tramadol can be explained by the fact that there is only slight first-pass metabolism. First-pass metabolism following oral administration is 30% at most.

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Distribution

Following oral use (100 mg) in liquid form, peak plasma concentrations (Cmax) after 1.2 hours are calculated to be 309 ± 90 ng/ml and following a similar dose in solid oral form peak plasma concentrations (Cmax) after 2 hours are 280 ± 49 ng/ml. Tramadol has high tissue affinity (Vd, β = 203 ± 40 l). Serum protein binding is approximately 20%.

Following the administration of MAXITRAM SR 100 mg peak plasma concentrations (Cmax) after 4.9 hours are 141 ± 40 ng/ml. Following the administration of MAXITRAM SR 200 mg, peak plasma concentrations (Cmax) after 4.8 hours are 260 ± 62 ng/ml.

Tramadol crosses the blood-brain barrier and the placenta. Very slight amounts of the drug together with its O-demethyl derivative are found in maternal milk (0.1% and 0.02% of the administered dose, respectively).

Biotransformation

In humans, tramadol is essentially metabolized by N- and O-demethylation as well as by conjugation of the O-demethylation products with glucuronic acid. Only O-demethyl tramadol is pharmacologically active. There are considerable quantitative interindividual variations as regards the other metabolites. 11 metabolites have been found in urine to date. According to results of animal experiments, O-demethyl tramadol exceeds the potency of the parent substance by a factor of 2 to 4. Its half-life (t½ β) (6 healthy volunteers) is 7.9 hours (ranging between 5.4 to 9.6 hours) and is similar to that of tramadol.

Inhibition of the isoenzymes CYP3A4 and/or CYP2D6 involved in the biotransformation of tramadol can influence the plasma concentration of tramadol or that of its active metabolites. Tramadol and its metabolites are almost completely excreted via the kidneys. Cumulative urinary excretion is 90% of the total radioactivity of the administered dose. Tramadol halflife may be slightly prolonged in patients with impaired liver or kidney function.

Elimination

half-lives of 13.3 ± 4.9 hours (tramadol) and of 18.5 ± 9.4 hours (O-demethyl tramadol) and in extreme cases of 22.3 and 36 hours, respectively have been determined in patients with cirrhosis of the liver. Elimination half-lives of 11 ± 3.2 hours and 16.9 ± 3 hours, and in extreme cases of 19.5 hours and 43.2 hours, respectively have been determined in patients with renal insufficiency (creatinine clearance < 5 ml/min).

Elimination

TRAMADOL CAPSULE 100 MG

The elimination half-life (t½ β) of tramadol is about 6 hours, irrespective of the method of administration. In patients over 75 years of age, elimination half-life may be prolonged by a factor of approx. 1.4.

5.3 Preclinical Safety Data.

None stated.

6. Pharmaceutical Particulars

6.1 List of Excipients

Lactose

BP
Talcum
BP
Cross povidone
BP Magnesium
Stearate BP
Sodium benzoate
BP PVP K30 BP
MCC102 BP
E.H.G. Capsule Size: 2 Green/Green BP

6.2 Incompatibilities
Non reported

6.3 Shelf Life
36 Months

6.4 Special Precautions for Storage
Store below 30° C. Place in dry place. Protect from light and moisture.

6.5 Nature and Contents of Container
10 capsules in one Blister. Such 01 Blisters in carton with insert and 10 mono carton in one outer carton

7. Marketing Authorization Holder and

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8. MARKETING AUTHORISATION NUMBER
CTD2162

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION NA

17-02-2026

10. DATE OF REVISION OF THE TEXT
26TH February, 2026