# 1.3 Product Information

# 1.3.1Summary of Product Characteristics (SmPC)

## 1. NAME OF THE MEDICINAL PRODUCT

**ZOTRAMA**

**(Tramadol Capsules BP 100 mg)**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Capsule Contains :

Tramadol Hydrochloride BP 100 mg

Approved Colours are used in capsule shell.

| UNIT FORMULA | | | |
|---|---|---|---|
| Raw Material | | Unit | Qty / Cap |
| Tramadol Hydrochloride | BP | mg | 100 |
| Purified Talc | BP | mg | 4.5 |
| Maize Starch | BP | mg | 24 |
| Magnesium Stearate | BP | mg | 1.5 |
| E.H.G. SIZE "4" Dark Green / Light Green Metallic Capsules | | No | 1 |

## 3. PHARMACEUTICAL FORM

Capsules

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Management of moderate to moderately severe pain.

## 4.2 Posology and method of administration

The dosage should be adjusted to the intensity of pain and the individual's response to the analgesic action of **ZOTRAMA (Tramadol Capsules BP 100 mg). ZOTRAMA (Tramadol Capsules BP 100 mg**) should not be used for the treatment of minor pain.
Adults and children over the age of 14 years:
Oral administration:
Moderate pain:
Initial dose of 50 mg, followed by 50 mg or 100 mg 4-6 hourly.
Moderately severe pain:
Initial dose of 50 mg or 100 mg followed by 50 mg or 100 mg 4-6 hourly. A total oral daily dose of more than 400 mg per day must not be exceeded.
Elderly:
The usual dosages may be used except in patients 75 years of age and over, a downward adjustment of the dose and/or prolongation of the interval between doses are recommended.
Renal impairment/renal dialysis:
The elimination of tramadol may be prolonged. It is recommended that the usual initial dosage be used. For patients with creatinine clearance <30 mL/min, the dosage interval should be increased to 12 hours. As tramadol is only removed very slowly by haemodialysis or haemofiltration, post dialysis administration to maintain analgesia is not usually necessary.
Hepatic impairment:
The elimination of tramadol may be prolonged. The usual initial dosage should be used but in severe hepatic impairment, the dosage interval should be increased to 12 hours.

## 4.3 Contraindications

ZOTRAMA (**Tramadol Capsules BP 100 mg**) is contra-indicated in known hypersensitivity to tramadol hydrochloride, or opioids, in acute intoxication with alcohol, hypnotics, analgesics or psychotropic medicines. It should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal.

ZOTRAMA (Tramadol Capsules BP 100 mg) must not be used for narcotic withdrawal treatment.
Safety during pregnancy and lactation has not been established.
ZOTRAMA (Tramadol Capsules BP 100 mg) should not be given to patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretions.

ZOTRAMA (Tramadol Capsules BP 100 mg ) should not be given to patients with increased intracranial pressure or central nervous system depression due to head injury or cerebral disease.

## 4.4 Pregnancy and lactation

Not Stated

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

The following side-effects have been reported:
Gastrointestinal system:
Nausea; vomiting; dry mouth; heartburn; constipation
Central Nervous System and Psychiatric:
Fatigue; sedation; drowsiness; dizziness; confusion; hallucinations; seizures (See Warnings)
Other:
Sweating (especially when intravenous administration is too rapid); skin rashes; bradycardia; tachycardia; flushing; bronchospasm; angioedema; syncope, anaphylaxis and anaphylactic reactions have been reported.
These reactions may occur after the first dose. Postural hypotension or cardiovascular collapse has been observed, potential for Toxic Epidermal Necrolysis and Stevens-Johnson syndrome. ZOTRAMA (Tramadol Capsules BP 100 mg ) should not be used for the treatment of minor pain.
Special Precautions:
Rapid intravenous administration may be associated with higher incidence of adverse events and should therefore be avoided. ZOTRAMA (Tramadol Capsules BP 100 mg) should be used with caution in patients with severe impairment of hepatic and renal function and in patients prone to convulsive disorders or in shock.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Tramadol Hydrochloride contains tramadol, a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, from animal tests, at least two complementary mechanisms appear applicable: binding of parent and M1 metabolite to μ-opioid receptors and weak inhibition of reuptake of norepinephrine and serotonin.

Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the O-demethylated metabolite M1 to μ-opioid receptors. In animal models, M1 is up to 6 times more potent than tramadol in producing analgesia and 200 times more potent in μ-opioid

binding. Tramadol-induced analgesia is only partially antagonized by the opiate antagonist naloxone in several animal tests. The relative contribution of both tramadol and M1 to human analgesia is dependent upon the plasma concentrations of each compound.

Tramadol has been shown to inhibit reuptake of norepinephrine and serotonin *in vitro,* as have some other opioid analgesics. These mechanisms may contribute independently to the overall

analgesic profile of Tramadol Hydrochloride. Analgesia in humans begins approximately within one hour after administration and reaches a peak in approximately two to three hours.

Apart from analgesia, Tramadol Hydrochloride administration may produce a constellation of symptoms (including dizziness, somnolence, nausea, constipation, sweating and pruritus) similar to that of other opioids. In contrast to morphine, tramadol has not been shown to cause histamine release. At therapeutic doses, Tramadol Hydrochloride has no effect on heart rate, left-ventricular function or cardiac index. Orthostatic hypotension has been observed.

### 5.2 Preclinical safety data

None stated.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

| Raw Material | |
|---|---|
| Purified Talc | BP |
| Maize Starch | BP |
| Magnesium Stearate | BP |
| E.H.G. SIZE “4” Dark Green / Light Green Metallic Capsules | |

### 6.2 Incompatibilities

None stated.

### 6.3 Shelf life

36 Months

### 6.4 Special precautions for storage

Store in a dry place below 30°C. Protect from light.

## 6.5 Nature and contents of container

10 x 10's Blister

## 7. MARKETING AUTHORISATION HOLDER

**Manufactured by:**
Navketan Pharma Pvt. Ltd.,
F -106, M.I.D.C. Area Waluj,
Dist. Aurangabad, Maharashtra, India

**Marketed by:**

**Mr Obidike E.Ifeanyi - M.D/CEO**

**BAKAN GIZO NIGERIA LTD.**

B13 A.M.A.C .OFFICE COMPLEX,WUSE ZONE 3,
ABUJA, F.C.T. NIGERIA

## 8. MARKETING AUTHORIZATION NUMBERS

Not Applicable

## . DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION :

Not Applicable

## 10. DATE OF REVISION OF THE TEXT :

Not Applicable