Trampa®

Paracetamol & Tramadol Hydrochloride

COMPOSITION

Trampa® Tablet: Each film coated tablet contains Paracetamol BP 325 mg & Tramadol Hydrochloride BP 37.50 mg.

PHARMACOLOGY

Tramadol is 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 M_1 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 M_1 to μ-opioid receptors. 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.
Paracetamol is a non-opiate, non-salicylate analgesic.

INDICATION

Trampa® tablet is indicated for the management of moderate to moderately severe pain in adults.
Trampa® tablet is also indicated for the short-term (five days or less) management of acute pain.

DOSAGE AND ADMINISTRATION

Trampa® tablet can be administered without regard to food.
For the management of moderate to moderately severe pain, the recommended dose is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.
In case of short-term (five days or less) management of acute pain, the recommended dose is 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.

CONTRAINDICATION

Tramadol & Paracetamol combination tablet should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, paracetamol, any other component of this product or opioids. This is contraindicated in any situation where opioids are contraindicated.

PRECAUTION

This combination preparation may impair mental or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. This combination preparation should not be taken with alcohol containing beverages. The patient should be instructed not to take this combination preparation in combination with other tramadol or paracetamol-containing products, including over-the-counter preparations. This combination preparation should be used with caution when taking medications such as tranquilizers, hypnotics or other opiate containing analgesics.

PEDIATRIC & GERIATRIC USE

The safety and effectiveness of this combination preparation has not been studied in the pediatric population.
In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function; of concomitant disease and multiple drug therapy.

Use in Renal Disease

This combination preparation has not been studied in patients with impaired renal function. In patients with creatinine clearances of less than 30 ml/min, it is recommended that the dosing interval of this combination preparation be increased but not to exceed 2 tablets every 12 hours.

Use in Hepatic Disease

This combination preparation has not been studied in patients with impaired hepatic function. The use of this combination preparation in patients with hepatic impairment is not recommended.

ADVERSE REACTIONS

The following adverse reactions may happen to this therapy: asthenia, fatigue, hot flushes, dizziness, headache, tremor, abdominal pain, constipation, diarrhea, dyspepsia, dry mouth, nausea, vomiting, anorexia, anxiety, confusion, euphoria, insomnia, nervousness, somnolence pruritus, rash, increased sweating etc.

USE IN PREGNANCY & LACTATION

Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. This combination preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

This combination preparation is not recommended for obstetrical preoperative medication or for post-delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied.

STORAGE

Store below 30°C in dry place. Keep away from light.
Keep out of reach of children.

HOW SUPPLIED

Trampa® Tablet: Each box contains 10 / 20 / 30 / 50 tablets in blister pack.

SQUARE