



MEDLEY PHARMACEUTICALS

CO-GESIC PLUS TABLETS

(PARACETAMOL+TRAMADOL HCl)

DESCRIPTION: CO-GESIC PLUS is a formulation of Paracetamol and Tramadol HCl in the form of Film Coated Tablets.

COMPOSITION:

CO-GESIC PLUS TABLETS:

Each Film Coated tablet contains:

Paracetamol.....325mg

Tramadol HCl.....37.5mg

(Medley's Specs.)

PHARMAKODYNAMICS:

Tramadol is a centrally acting synthetic analgesic compound whose analgesic profile can be attributed to the binding of parent and O-demethylate (M 1) metabolite to u-opioid receptors as well as the weak inhibition of neuronal reuptake of noradrenalin and serotonin. Paracetamol inhibits the synthesis of prostaglandins in the CNS and blocks the pain impulses generated peripherally.

INDICATIONS:

Treatment of mild to moderate, acute and chronic pain (Treatment for three days or less).

CONTRAINDICATIONS:

Known hypersensitivity to Tramadol, Paracetamol or other opioids such as codeine. It is also contraindicated in cases of severe liver function impairment and in acute intoxications with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic medicines. It should not be administered to patients who are receiving MAO inhibitors or within two week of their withdrawal. Must not be used for narcotic withdrawal treatment. Should not be given to the patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretions. Should not be given to the patients with increased intracranial pressure or CNS depression due to head injury or cerebral disease..

PREGNANCY AND LACTATION: Safety during pregnancy and lactation has not been established. Tramadol has been shown to cross the placenta.

DOSAGE AND DIRECTIONS FOR USE:

To use in adults and children over 16 years of age do not exceed the recommended dose.



Manufactured by:
ISO 9001-2008 Certified Company
Medley Pharmaceuticals
41-A, P.S.I.E. Jhang Bahtar Road,
Wah Cantt- Rawalpindi



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ACUTE PAIN: Two tablets every 4-6 hours as needed for pain relief. Do not exceed 8 Tablets per day.

RENAL IMPAIRMENT: For patients with creatinine clearance less than 30ml/min, the dosing interval should be increased not exceeding two tablets every 12 hours.

NOTE: Not recommended for use in children.

PRECAUTION: Do not co-administer with other Tramadol or Paracetamol containing products. Should not be taken with beverages that contain alcohol. Concurrently with CNS depressants such as alcohol, opioids, anesthetic agents, phenothiazines, tranquilizers or sedative hypnotics is likely to intensify and prolong CNS effects. Patients with impaired renal function and patients prone to convulsive disorders or in shock.

SIDE EFFECTS:

GIT: Nausea, abdominal pain, constipation, flatulence, vomiting, dry mouth, dyspepsia and diarrhea.

CNS: Dizziness, headache, nervousness, anxiety, agitation, euphoria, emotional lability, hallucinations, hypertonia and tremors, somnolence and insomnia, anorexia, confusion.

Others reported side effects include pruritus, fatigue, Upper Respiratory tract infections, increased sweating, hot flushes, rashes and asthenia. The side effects reported with the use of tramadol include anaphylaxis, increased liver enzymes values, postural hypotension or cardiovascular collapse and the potential for toxic epidermal necrolysis and Stevens-Johnson's syndrome. Paracetamol may cause allergic reactions and skin rash. The rash usually occurs as red area of allergic wheals and may be accompanied by fever and involvement of mucous membranes. The use of Paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

INTERACTIONS:

Carbamazepine may significantly decrease Tramadol and M1 concentrations. Patients receiving carbamazepine may have significantly reduced analgesic effects from the Tramadol. Inhibitors of CYP2D6 such as Fluoxetine, Paroxetine, Quinidine and Amitriptyline could result in some inhibition of Tramadol. Simultaneous administration with cimetidine is associated with clinically insignificant changes in serum concentrations of Tramadol.

STORAGE:

Keep in a cool and dry place.

Protect from light.

Keep out of the reach of children.

PRESENTATION:

Alu-Alu Blister packs of 1 × 10's tablets.



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