Dulcet

[Tramadol HCl /Paracetamol]
37.5mg/325mg
Tablets

ڈلسٹ

۳۷.۵ ملی گرام/۳۲۵ ملی گرام
گولیاں

COMPOSITION
Tramadol HCl USP.....37.5mg
Paracetamol BP.....325mg
(Product Specs. : USP)

CLINICAL PHARMACOLOGY:

PHARMACODYNAMICS:
Tramadol HCl is a centrally acting synthetic analgesic compound whose analgesic profile can be attributed to the binding of parent and 0-demethylated (M1) metabolite to μ-opioid receptors as well as the weak inhibition of neuronal re-uptake of noradrenaline and serotonin. Paracetamol also has centrally acting analgesic effects.

PHARMACOKINETICS:
Tramadol HCl is well absorbed after oral administration, reaching peak
activity in 2 to 3 hours. Oral absorption of Paracetamol following co-administration of Tramadol HCl and Paracetamol, gives a peak plasma concentration of Paracetamol within one hour and is not affected by co-administration with Tramadol HCl . Tramadol HCl and Paracetamol are both extensively metabolized in the liver. Approximately 30% of Tramadol HCl is excreted unchanged in the urine. Tramadol HCl and its metabolites are eliminated primarily by the kidney. The plasma elimination half-lives of Tramadol HCl and its M1 metabolite are approximately 6 and 7 hours respectively. Paracetamol is eliminated from the body primarily by formation of glucuronide and sulfate conjugates in a dose-dependent manner. The half-life of Paracetamol is about 2-3 hours in adults. Less than 9% of Paracetamol is excreted unchanged in the urine.

INDICATIONS:
DULCET Tablets are indicated for the short term (5 days or less) management of acute pain.

DOSAGE AND ADMINISTRATION:
To be used in adults and children over 16 years of age. Do not exceed the recommended dose.
Acute Pain:
2 tablets every 4 to 6 hours as needed for pain relief. Do not exceed 8 tablets per day.
Renal Impairment:
In patients with creatinine clearance less than 30ml/min, it is recommended that the dosing interval be increased not to exceed 2 tablets every 12 hours or as directed by the Physician.

CONTRAINDICATIONS:
Tramadol HCl / Paracetamol combination is contraindicated in patients with a known hypersensitivity to Tramadol HCl , Paracetamol or other opioids such as codeine. It is also contraindicated in cases of severe liver function impairment and in acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic medicines. It should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal.
Tramadol HCl /Paracetamol combination must not be used for narcotic withdrawal treatment.
Tramadol HCl /Paracetamol combination should not be given to patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretions.
Tramadol HCl /Paracetamol combination should not be given to patients with increased intracranial pressure or central nervous system depression due to head injury or cerebral disease.

WARNINGS:
Dosage in excess of those recommended may cause severe liver damage. Patients suffering from liver or kidney disease should take Paracetamol containing products under medical supervision.

Serious Skin Reactions:
Rarely, Paracetamol may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens- Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Seizures:
Seizures have been reported in patients receiving Tramadol HCl at dosages within the recommended dosage range. The risk of seizures is enhanced in patients exceeding the recommended dose, or in patients taking tricyclic anti-depressants or other tricyclic compounds e.g. promethazine, selective serotonin re-uptake inhibitors, MAO-inhibitors and neuroleptics.

Drug Abuse and Dependence:
Although Tramadol HCl has a low dependence potential, tolerance, psychic and physical dependence of the morphine-type (μ-Opioid) may develop with long-term use.

Effects on Ability to drive or Operate Machinery:
Tramadol HCl 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.

SPECIAL PRECAUTIONS:
Do not co-administer **DULCET** with other Tramadol HCl or Paracetamol containing products. Tramadol HCl /Paracetamol combination should not be taken with alcohol containing beverages. The administration of Tramadol HCl /Paracetamol concurrently with central nervous system (CNS) depressants such as alcohol, opioids anesthetic agents, Phenothiazines, tranquilizers or sedative hypnotics is likely to intensify and prolong CNS effects. Tramadol HCl /Paracetamol combination should be used with caution in patients with impaired renal functions, in patients with impaired hepatic functions and in patients prone to convulsive disorders or in shock.

PRECAUTIONS:

Pregnancy:
Teratogenic Effects: Pregnancy Category C
Safety during pregnancy and lactation has not been established. Tramadol HCl has been shown to cross the placenta.

Children:
Safety and efficacy have not been established.

Elderly:
Use with caution, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease and multiple drug therapy.

DRUG INTERACTIONS:
Concomitant administration of Tramadol HCl / Paracetamol combination and carbamazepine may cause significantly decreased Tramadol HCl and M1 concentrations. Patients receiving carbamazepine may have significantly reduced analgesic effect from the Tramadol HCl component of Tramadol HCl /Paracetamol combination.
Concomitant administration with inhibitors of CYP2D6 such as fluoxetine, paroxetine, quinidine and amitriptyline could result in some inhibition of the metabolism of Tramadol HCl. Simultaneous administration with cimetidine is associated with clinically insignificant changes in serum concentrations of Tramadol HCl. Therefore no alteration of the Tramadol HCl / Paracetamol dosage regimen is recommended for patients receiving chronic cimetidine therapy. Tramadol HCl / Paracetamol combination must not be combined with a MAO-inhibitor, or within 14 days of discontinuation of it, as potentiation of serotonergic and noradrenergic effects may result.
Periodic evaluation of prothrombin time should be performed when Tramadol HCl / Paracetamol is administered concurrently with warfarin like compound. Concomitant administration of diflunisal and Paracetamol produces a 50% increase in Paracetamol plasma levels in normal volunteers. Tramadol HCl /Paracetamol combination should be used cautiously and patients should be monitored carefully.

SIDE EFFECTS:
The most frequently reported side effects were of the gastrointestinal and central nervous system. These include:

Gastrointestinal System:
Nausea, abdominal pain, constipation, flatulence, vomiting, dry mouth, dyspepsia and diarrhoea.

Central Nervous System and Psychiatric:
Dizziness, headache, anxiety, agitation, emotional lability, hallucinations, hypertonia and tremor. Somnolence, insomnia, anorexia, anxiety, confusion, euphoria and nervousness.
Other reported side-effects include pruritus, fatigue, upper respiratory tract infection, increased sweating, hot flushes, rashes and asthenia.Other side-effects reported with the use of Tramadol HCl include anaphylaxis, increased liver enzyme values, postural hypotension or cardiovascular collapse and the potential for Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome. Paracetamol may cause allergic reactions and skin rash. The rash usually appears as red areas or allergic and may be accompanied by fever and involvement of the mucous membranes. The use of Paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

OVERDOSAGE:
Treatment of overdose requires the maintenance of the airway and cardiovascular functions. Respiratory depression may be reversed using naloxone and fits controlled with diazepam. The treatment of acute overdose of Tramadol HCl using hemodialysis or hemofiltration alone is not sufficient or suitable due to the slow elimination of Tramadol HCl from the serum by these routes.
NAC (N-acetylcysteine) antidote of Paracetamol, should be administered orally or intravenously as quickly as possible.

INSTRUCTION:
Store below 30°C.
Protect from light and moisture.
Keep out of reach of children.
To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED
DULCET Tablets are available in pack of 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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