Fevedol

Tablet

DRUG INTERNATIONAL LTD.

Composition : Each Film Coated Tablet Contains Paracetamol (Acetaminophen) USP 325mg and Tramadol Hydrochloride USP 37.50mg.

Pharmacology : Acetaminophen is a non-opioid, non-salicylate analgesic. The site and mechanism for the analgesic effect of acetaminophen has not been determined but is thought to primarily involve central actions. Peak plasma concentrations of acetaminophen occur within one hour and are not affected by coadministration with tramadol. Acetaminophen appears to be widely distributed throughout most body tissues except fat. Its apparent volume of distribution is about 0.9 L/kg. A relative small portion (~20%) of acetaminophen is bound to plasma protein. Acetaminophen is eliminated from the body primarily by formation of glucuronide and sulfate conjugates in a dose dependent manner. Acetaminophen is primarily metabolized in the liver by first-order kinetics and involves three principal separate patnways. Less than 9% of acetaminophen is excreted unchanged in the urine. Although the mode of action of tramadol is not completely understood, the analgesic effect of tramadol is believed to be due to both binding to μ-opioid receptors and weak inhibition of reuptake of norepinephrine and serotonin. Tramadol has a mean absolute bioavailability of approximately 75% following administration of a single 100 mg oral dose of this combined tablets. The binding of tramadol to human plasma proteins is approximately 20%. Tramadol is eliminated primarily through metabolism by the liver and the metabolites are eliminated primarily by the kidneys. Following oral administration, tramadol is extensively metabolized by a number of pathways, including CYP2D6 and CYP3A4, as well as by conjugation of parent and metabolites. Approximately 30% of the tramadol dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

Indications : It is indicated for the symptomatic treatment of moderate to severe pain.

Dosage and administration : It should be used in adults and children over 12 years of age. The recommended dose should not be exceeded. The recommended dose is 2 tablets every 6 hours as needed for pain relief up to a maximum of 8 tablets per day. Or, as directed by the registered physician.

Contraindication : This medicine is contra-indicated in patients with a known hypersensitivity to tramadol, paracetamol or other opioids such as codeine.

Precautions : The administration of this medicine concurrently with central nervous system (CNS) depressants such as alcohol, opioids, anaesthetic agents, phenothiazines, tranquilizers or sedative hypnotics is likely to intensify and prolong CNS effects. It should be used with caution in patients with impaired renal function and in patients prone to convulsive disorders or in shock.

Side effects : The most common adverse reactions are abdominal pain, diarrhea, constipation, flatulence, vomiting, dry mouth, dyspepsia, fatigue.

Use in Pregnancy and lactation : It has been assigned to pregnancy category C by the FDA. It can be used in pregnancy if potential benefits outweigh the risk or as directed by the registered physician. It is likely to be excreted into the breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

Use in Child : There is no data available.

Drug Interactions : Concomitant administration of this medicine and carbamazepine may cause significantly decreased tramadol and MI concentrations. Patients receiving carbamazepine may have significantly reduced analgesic effect from the tramadol component of this medicine. Concomitant administration with inhibitors of CYP2D6 such as fluoxetine, paroxetine, quinidine and amitriptyline could result in some inhibition of the metabolism of tramadol.

Overdose : In case of overdose, the symptoms may include the signs and symptoms of toxicity of tramadol or paracetamol or of both these active ingredients.

Storage : Store below 30°C in a dry place.

Packing : Each box contains 3 x 10's tablets in blister pack.