# P-DOL Tablets

**Tramadol HCL 37.5mg Paracetamol 325mg**

# پی۔ڈول ٹیبلیٹس

(ٹریماڈول ہائیڈروکلورائیڈ ۳۷.۵ ملی گرام + پیراسٹامول ۳۲۵ ملی گرام)

**COMPOSITION:**

Each film coated tablet contains:

**Tramadol HCl**.....**37.5mg**
**Paracetamol** .....**325mg**
Specifications: USP

**CLINICAL PHARMACOLOGY:**

**Mode of Action**

Tramadol 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 is well absorbed after oral administration, reaching peak activity in 2 to 3 hours. Oral absorption of paracetamol following co-administration of tramadol and paracetamol, gives a peak plasma concentration of paracetamol within one hour and is not affected by co-administration with tramadol Tramadol and paracetamol are both extensively metabolised in the liver. Approximately 30% of tramadol is excreted unchanged in the urine. Tramadol and its metabolites are eliminated primarily by the kidney. The plasma elimination half-lives of tramadol 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:**

**P-DOL** tablets are indicated for the short term (Less than 5 days) management of acute pain

**CONTRAINDICATIONS:**

Tramadol + Paracetamol combination is contraindicated in patients with a 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 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 + Paracetamol combination must not be used for narcotic withdrawal treatment

Tramadol + Paracetamol combination should not be given to patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretions

Tramadol + 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:**

Dosages 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, acetaminophen (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 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 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 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

**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

**SIDE-EFFECTS:**

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

**Gastrointestinal System**

Nausea, abdominal pain, constipation, flatulence, vomiting, dry mouth, dyspepsia and diarrhoea

**Central Nervous System and Psychiatric**

Dizziness, headache, nervousness, anxiety, agitation, euphoria, 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 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 wheals, 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

**PRECAUTIONS:**

**Pregnancy**

**Teratogenic Effects**: Pregnancy Category C

Safety during pregnancy and lactation has not been established. Tramadol 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

**SPECIAL PRECAUTIONS:**

Do not co-administer **P-DOL** with other tramadol or paracetamol containing products. Tramadol + Paracetamol combination should not be taken with alcohol containing beverages.The administration of tramadol + paracetamol combination 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

Tramadol + 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

**DRUG INTERACTIONS:**

Concomitant administration of tramadol + paracetamol combination and carbamazepine may cause significantly decreased tramadol and M1 concentrations. Patients receiving carbamazepine may have significantly reduced analgesic effect from the tramadol component of tramadol + 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

Simultaneous administration with cimetidine is associated with clinically insignificant changes in serum concentrations of tramadol. Therefore, no alteration of the tramadol + paracetamol dosage regimen is recommended for patients receiving chronic cimetidine therapy

Tramadol + 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 + paracetamol is administered concurrently with warfarin like compounds

Concomitant administration of diflunisal and paracetamol produces a 50% increase in paracetamol plasma levels in normal volunteers.

Tramadol + Paracetamol combination should be used cautiously and patients should be monitored carefully

**PRESENTATION:**

**P-DOL** tablets in a pack of 10's and 20's.

**STABILITY:**

See expiry on the pack

**INSTRUCTIONS:**

Keep out of the reach of children

Avoid exposure to heat, light and humidity

Store below 30°C.

Improper storage may deteriorate the medicine

Manufactured by :

PHARMA LORD

PHARMA LORD (PVT.) LIMITED | 12km, Lahore Road, Layyah. Pakistan

www.pharma-lord.com

# پی۔ڈول ٹیبلٹ

(ٹریماڈول ہائیڈروکلورائیڈ ۳۷.۵ ملی گرام + پیراسٹامول ۳۲۵ ملی گرام)

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات : بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ

درجہ حرارت پر رکھیں ورنہ دوا خراب ہو جائے گی۔