DOMADOL PLUS

To be sold by retail on the prescription of R.M.P. only

Abbreviated Prescribing information for DOMADOL PLUS (FDC of Acetaminophen 325 mg & Tramadol Hydrochloride 37.5 mg Film Coated Tablets**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

Qualitative and Quantitative composition for DOMADOL PLUS

Each film-coated tablet contains:

Tramadol Hydrochloride I.P. ….....37.5 mg

Paracetamol I.P. ……....325 mg

Excipients……q.s.

Colour: Yellow Oxide of Iron USPNF

The excipients used are Starch, Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone K-30, Colloidal Silicon Dioxide, Talc, Magnesium Stearate, Opadry 03B82982 Yellow, Isopropyl Alcohol and Dichloromethane.

PHARMACOLOGICAL PROPERTIES:

Mechanism of action:

Paracetamol:

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears however to be on a selective basis. The precise mechanism of the analgesic properties of paracetamol is unknown and may involve central and peripheral effects.

Tramadol:

Tramadol is an opioid analgesic that acts on the central nervous system. Tramadol is a pure non selective agonists of the μ, δ, and κ opioid receptors with a higher affinity for the μ receptors. Other mechanisms which contribute to its analgesic effect are inhibition of neuronal reuptake of noradrenaline and enhancement of serotonin release.

THERAPEUTIC INDICATION:

It is indicated for short term (five days or less) management of acute pain in adults.

DOSAGE AND ADMINISTRATION:

Dosage: The dose should be adjusted to intensity of pain and the sensitivity of the individual patient. An initial dose of two tablets of Tramadol hydrochloride/Paracetamol is recommended. Additional doses can be taken as needed, not exceeding 8 tablets (equivalent to 300 mg tramadol and 2600 mg paracetamol) per day. The dosing interval should not be less than six hours.

Method of administration: For oral use. Tablets must be swallowed whole, with a sufficient quantity of liquid. They must not be broken or chewed.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, • acute intoxication with alcohol, hypnotic drugs, centrally-acting analgesics, opioids or psychotropic drugs, • Tramadol hydrochloride/Paracetamol should not be administered to patients who are receiving monoamine oxidase inhibitors or within two weeks of their withdrawal, • severe hepatic impairment, • epilepsy not controlled by treatment.

WARNINGS & PRECAUTIONS: In order to avoid inadvertent overdose, patients should be advised not to exceed the recommended dose and not to use any other paracetamol (including over the counter) or tramadol hydrochloride containing products concurrently without the advice of a physician. • In severe renal insufficiency (creatinine clearance <10 ml/mm), Tramadol hydrochloride/Paracetamol is not recommended. • In patients with severe hepatic impairment Tramadol hydrochloride/Paracetamol should not be used. • In severe respiratory insufficiency, Tramadol hydrochloride/Paracetamol is not recommended. • Convulsions have been reported in patients receiving tramadol at the recommended dose levels. • Concomitant use of opioid agonists-antagonists (nalbuphine, buprenorphine, etazocine) is not recommended. • Tolerance and physical and/or psychological dependence may develop, even at therapeutic doses. • Paracetamol in over dosage may cause hepatic toxicity in some patients. • Symptoms of withdrawal reaction, similar to those occurring during opiate withdrawal, may occur even at therapeutic doses and for short term treatment.

DRUG INTERACTION: Concomitant use is contraindicated with:

• Non-selective MAO Inhibitors

Risk of serotonergic syndrome: diarrhoea, tachycardia, hyperhidrosis, trembling, confusional state, even coma.

• Selective-A MAO Inhibitors

Extrapolation from non-selective MAO inhibitors

Risk of serotonergic syndrome: diarrhoea, tachycardia, hyperhidrosis, trembling, confusional state, even coma.

• Selective-B MAO Inhibitors

Central excitation symptoms evocative of a serotonergic syndrome: diarrhoea, tachycardia, hyperhidrosis, trembling, confusional state, even coma.

Concomitant use is not recommended with:

• Alcohol

Alcohol increases the sedative effect of opioid analgesics.

• Carbamazepine and other enzyme inducers

Risk of reduced efficacy and shorter duration due to decreased plasma concentrations of tramadol.

• Opioid agonists-antagonists (buprenorphine, nalbuphine, pentazocine)

Decrease of the analgesic effect by competitive blocking effect at the receptors, with the risk of occurrence of withdrawal syndrome.

Concomitant use which needs to be taken into consideration:

• Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic

antidepressants, antipsychotics and seizure threshold-lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.

• Concomitant therapeutic use of tramadol and serotonergic drugs such as selective serotonin re-uptake inhibitors (SSRIs) serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors, tricyclic antidepressants and mirtazapine may cause serotonin toxicity.

• Other opioid derivatives (including antitussive drugs and substitutive treatments), benzodiazepines and barbiturates

Increased risk of respiratory depression which can be fatal in cases of overdose.

• Other central nervous system depressants, such as other opioid derivatives (including antitussive drugs and substitutive treatments), barbiturates, benzodiazepines, other anxiolytics, hypnotics, sedative antidepressants, sedative antihistamines, neuroleptics, centrally-acting antihypertensive drugs, thalidomide and baclofen.

These drugs can cause increased central depression. The effect on alertness can make driving of vehicles and the use of machines dangerous.

ADVERSE REACTIONS: palpitations, tachycardia, arrhythmia, vision blurred, miosis, mydriasis, tinnitus, nausea, vomiting, constipation, dry mouth, diarrhea, abdominal pain, dyspepsia, flatulence, dysphagia, melaena, chills, chest pain, transaminases increased, hypoglycaemia, dizziness, somnolence, headache trembling, involuntary muscular contractions, paraesthesia, amnesia, confusional state, mood altered, anxiety, nervousness, euphoric mood), sleep disorders, depression, hallucinations, nightmares, delirium, drug dependence, drug abuse, albuminuria, micturition disorders (dysuria and urinary retention), dyspnea, hyperhidrosis, pruritus, dermal reactions (e.g. Rash, urticaria), hypertension, hot flush, Postural hypotension, bradycardia, collapse, anaphylaxis, changes in appetite, motor weakness, respiratory depression, blood dyscrasias including thrombocytopenia and agranulocytosis, hypoprothrombinaemia, changes in mood, changes in cognitive and sensorial capacity, Symptoms of drug withdrawal syndrome, similar to those occurring during opiate withdrawal.

STORAGE: Store in a cool, dry place. Protect from light. Keep out of reach of children.

Marketed BY:

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IN/ DOMADOL PLUS 37.5 mg and 325 mg /May-20/01/ABPI
(Additional information is available on request)