DOMADOL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for DOMADOL [Tramadol Capsules I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tramadol, a cyclohexanol derivative, is a centrally acting analgesic which possesses opioid agonist properties. Tramadol appears to modify the transmission of pain impulses by inhibition of monoamine reuptake. Tramadol also has an antitussive action but has no effect on gastrointestinal motility.

INDICATIONS: Analgesic- For severe acute and chronic pain, diagnostic measures and surgical pain.

DOSAGE AND ADMINISTRATION: Domadol Capsules 50 mg should be adjusted to the intensity of the pain and the sensitivity of the individual patient. For acute pain initial dose of 100mg is usually necessary. Pain Associated with Chronic Conditions an initial dose of 50mg is advised and then titration according to pain severity. Paediatric population tramadol Hydrochloride capsules are not suitable for children below the age of 12 years. In patients with renal and/or hepatic insufficiency the elimination of tramadol is delayed, so prolongation of the dosage intervals should be carefully considered. For creatinine clearance <30 ml/min the dosing should be increased to 12 hourly intervals. For creatinine clearance <10 ml/min (severe renal impairment) Domadol 50 mg capsules are not recommended. The capsules are to be taken whole with sufficient liquid, independently of meals. Swallow the capsules whole with some water without chewing. If you have difficulty in swallowing, you may open the capsules. Do not chew. Swallow all the pellets with water.

CONTRAINDICATION: Acute intoxication with alcohol, hypnotics, analgesics, opioids, or other psychotropic medicinal products). Patients who are receiving MAO inhibitors or who have taken them within the last 14 days. In patients with epilepsy not adequately controlled by treatment. For use in narcotic withdrawal treatment. Hypersensitivity to the active substance or any of the excipients.

WARNINGS & PRECAUTIONS: DOMADOL may only be used with particular caution in opioid-dependent patients, patients with head injury, shock, a reduced level of consciousness of uncertain origin, disorders of the respiratory centre or function, increased intracranial pressure. Care should be taken when treating patients with respiratory depression, or if concomitant CNS depressant drugs are being administered, or if the recommended dosage is significantly exceeded as the possibility of respiratory depression cannot be excluded in these situations. Convulsions have been reported in patients receiving tramadol at the recommended dose levels. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg). In addition, tramadol may increase the seizure risk in patients taking other medicinal products that lowers the seizure threshold. Patients with epilepsy or those susceptible to seizures should only be treated with tramadol if there are compelling circumstances. Tramadol may increase the seizure risk in patients taking other medicinal products that lowers the seizure threshold. In patients with a tendency to drug abuse or dependence, treatment with tramadol should only be carried out for short periods under strict medical supervision. DOMADOL is not a suitable substitute in opioid dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms. When a patient no longer requires therapy with tramadol, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. Tramadol is metabolised by the liver enzyme CYP2D6. If a patient has a deficiency or is completely lacking this enzyme an adequate analgesic effect may not be obtained. If the patient is an ultra-rapid metaboliser there is a risk of developing side effects of opioid toxicity even at commonly prescribed doses. opioid toxicity include confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life threatening and very rarely fatal. There have been reports in the published literature that tramadol given post-operatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, led to rare, but life threatening adverse events. Tramadol is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures. Concomitant use of DOMADOL and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Tramadol should be used for severe acute pain only for a period not exceeding 5 days.

DRUG INTERACTIONS: DOMADOL should not be combined with MAO inhibitors. Simultaneous or previous administration of carbamazepine (enzyme inducer) may reduce the analgesic effect and shorten the duration of action. Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs),

serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other 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 reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors, tricyclic antidepressants and mirtazapine may cause serotonin toxicity. Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives (e.g. warfarin) due to reports of increased INR with major bleeding and ecchymoses in some patients. The administration of DOMADOL with other centrally depressant medicinal products, including alcohol, may potentiate the CNS effects. The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect.

ADVERSE REACTIONS: Cardiovascular regulation (palpitation, tachycardia). These adverse reactions may occur especially on intravenous administration and in patients who are physically stressed, bradycardia, increase in blood pressure, postural hypotension or cardiovascular collapse, changes in appetite, hypoglycaemia, respiratory depression, dyspnoea, Hiccups, dizziness, paraesthesia, tremor, respiratory depression, epileptiform convulsions, involuntary muscle contractions, abnormal coordination, syncope, speech disorders, Convulsions occurred mainly after administration of high doses of tramadol or after concomitant treatment with medicinal products which can lower the seizure threshold, hallucinations, confusion, sleep disturbance, delirium, anxiety and nightmares. Psychological adverse reactions may occur following administration of DOMADOL which vary individually in intensity and nature (depending on personality and duration of treatment). These include changes in mood (usually elation, occasionally dysphoria), changes in activity (usually suppression, occasionally increase) and changes in cognitive and sensorial capacity (e.g. decision behaviour, perception disorders). Dependence may occur. Symptoms of withdrawal reactions, similar to those occurring during opiate withdrawal, may occur as follows: agitation, anxiety, nervousness, insomnia, hyperkinesia, tremor and gastrointestinal symptoms. Other symptoms that have very rarely been seen with tramadol discontinuation include: panic attacks, hallucinations, paresthesias, tinnitus and unusual CNS symptoms (i.e. delusions, depersonalisation, derealisation, paranoia), miosis, mydriasis, blurred vision, vomiting, constipation, dry mouth, retching; gastrointestinal irritation (a feeling of pressure in the stomach, bloating), diarrhoea, sweating, motorial weakness, increase in liver enzyme values has been reported in a temporal connection with the therapeutic use of tramadol, micturition disorders (difficulty in passing urine, dysuria and urinary retention), allergic reactions (e.g. dyspnoea, bronchospasm, wheezing, angioneurotic oedema) and anaphylaxis, fatigue.

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(Additional information is available on request)