Marol (Tramadol Hydrochloride) Prolonged Release tablets
Abbreviated Prescribing Information

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Morningside Healthcare Limited

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Presentation: Prolonged-release tablets containing 100 mg, 150 mg or 200 mg tramadol hydrochloride. **Indications:** Treatment of moderate to severe pain. **Dosage and administration:** Adjust dose to severity of pain and individual response. Swallow whole, independent of meals, with sufficient liquid. *Adults and adolescents over 12 years:* Initially 100 mg twice daily. Subsequent doses may be administered earlier than 12 hours, but not less than 8 hours after previous dose. If required dose may be increased to 150 mg, twice daily or 200 mg, twice daily. Do not use for longer than necessary. *Children under 12 years:* Not recommended. *Elderly:* No dose adjustment necessary. In older patients (above 75 years) dose interval may be prolonged if elimination is delayed. *Renal impairment, dialysis and hepatic impairment:* Moderate impairment-consider adjustment of dose interval. Serious impairment-not recommended. **Contraindications:** Hypersensitivity to tramadol, or any excipients. Acute intoxication with alcohol, hypnotics, analgesics, opioids or psychotropic drugs. Patients receiving MAO inhibitors, or within 2 weeks of their withdrawal. Do not use for narcotic withdrawal treatment. **Precautions and warnings:** Caution in patients dependent on opioids, patients with head injuries, shock, decreased level of consciousness of unknown origin, disturbances of the respiratory centre or function, or increased intracranial pressure and patients sensitive for opioids. Convulsion risk may be increased at doses exceeding 400 mg. Patients with a history of epilepsy or those susceptible to seizures should only be treated with tramadol if there are compelling reasons. Tramadol has a low dependence potential. In patients with a tendency to drug abuse or dependence, treatment should be for short periods under strict medical supervision. Tramadol is not a suitable substitute in opioid dependent patients and does not suppress morphine withdrawal symptoms. **Interactions:** Do not combine with MAO inhibitors. Consider potentiation of CNS effects when Marol Prolonged-release tablets and other centrally acting drugs are used. Concomitant or prior use of carbamazepine may reduce the analgesic effectiveness and shorten the duration of the action. The combination of mixed agonists/antagonists and tramadol is not recommended. Tramadol may induce convulsions and may increase the potential for selective serotonin re-uptake inhibitors, tricyclic antidepressants, anti-psychotics and other seizure threshold lowering drugs to cause convulsions. Isolated cases of serotonergic syndrome have been reported with the use of tramadol in combination with other serotonergic agents such as selective serotonin re-uptake inhibitors. Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives. Other medicinal products with a known inhibiting effect on CYP3A4, such as ketoconazole and erythromycin, could inhibit the metabolism of tramadol and probably also the metabolism of it's active metabolite. **Pregnancy and lactation:** Not recommended. A once only administration of tramadol does not usually require the discontinuation of breastfeeding. **Effects on Ability to Drive and Use Machines:** May cause drowsiness, patients should be warned not to drive or use machinery if affected. **Adverse reactions:** *Very common:* Dizziness and nausea. *Common:* Headache, drowsiness, vomiting, constipation, dry mouth and sweating. *Serious:* Effects on cardiovascular regulation (palpitation, tachycardia, postural hypotension or cardiovascular collapse). Respiratory depression and epileptiform convulsions. Hallucinations, confusion, blurred vision and increase in liver enzymes. Micturition disorders (difficulty in passing urine and urinary retention). Allergic reactions (e.g. dyspnoea, bronchospasm, wheezing, angioneurotic oedema) and anaphylaxis. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** Symptoms include miosis, vomiting, cardiovascular collapse, narrowing of consciousness leading to coma, convulsions, respiratory depression leading to respiratory failure. Treatment is maintenance of the airway (aspiration), maintenance of respiration and cardiovascular circulation depending on the symptoms and emptying of the stomach. The antidote for respiratory depression is naloxone. If naloxone proves ineffective against convulsions, diazepam should be administered intravenously. **NHS Price:** Packs of 60, Marol 100 mg Prolonged-release tablets £6.98; Packs of 60, Marol 150 mg Prolonged-release tablets £10.48, Packs of 60, Marol 200 mg Prolonged-release tablets £14.28. **Legal category:** POM. **Marketing Authorisation Numbers:** Marol 100 mg Prolonged-release tablets PL 20117/0045, Marol 150 mg Prolonged-release tablets PL 20117/0046, Marol 200 mg Prolonged-release tablets PL 20117/0047. **Marketing Authorisation Holder:** Morningside Healthcare Limited, 115 Narborough Road, Leicester, LE3 0PA, UK. **Date of preparation:** March 2014. **Job Code:** UK/MED/14/0015.