Prescribing Information

Nefopam hydrochloride 60 mg film-coated tablets

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Presentation: Each film-coated tablet contains 60 mg nefopam hydrochloride. For the full list of excipients, refer to the SmPC

Indications: For the relief of acute and chronic pain, including post-operative pain, dental pain, musculo-skeletal pain, acute traumatic pain and cancer pain.

Dosage and administration: Adult: The recommended starting dosage is 1 tablet of 60mg three times daily. 30mg to 90mg three times daily depending on response.

Special Populations: The safety and efficacy of Nefopam hydrochloride in children under 12 years has not yet been established. No dosage recommendation can be given for patients under 12 years. Older patients may require reduced dosage due to slower metabolism. Patients with end stage renal disease might experience increased serum peak concentrations during treatment with nefopam. In order to avoid that, it is recommended the daily dose should be reduced not only for the elderly, but also for patients with terminal renal insufficiency.

Method of Administration: Oral use
Fertility, pregnancy and lactation There is no evidence as to the drug safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. Avoid in pregnancy unless there is no safer treatment.

Contraindications: patients with a history of convulsive disorders and should not be given to patients taking mono-amine-oxidase (MAO) inhibitors and patients with known hypersensitivity to any of the ingredients.

Special warnings and precautions: The side effects of the drug may be additive to those of other agents with anticholinergic or sympathomimetic activity. It should not be used in the treatment of myocardial infarction since there is no clinical experience in this indication. Hepatic and renal insufficiency may interfere with the metabolism and excretion of nefopam. Has to be used with caution in patients with angle closure glaucoma. Cases of nefopam dependence and abuse have been reported with nefopam use. Should be used with caution in patients with, or at risk of, urinary retention. Rarely a temporary, harmless pink discolouration of the urine has occurred. This product is not suitable for patients requiring the dose of 30mg as the product cannot be divided into two equal halves.

Drug Interactions: Caution should be taken when concurrently administered with tricyclic antidepressants. It may interfere with some screening tests for benzodiazepines and opioids. These tests for benzodiazepines and opioids may give false positive results.

Effects on ability to drive/use machines: Not applicable.

Undesirable effects: Nausea, nervousness, dry mouth and light-headedness, urinary retention, hypotension, syncope, palpitations, gastrointestinal disturbances (including abdominal pain and diarrhoea), dizziness, paraesthesia, convulsions, tremor, confusion, hallucination, angioedema, and allergic reactions may occur. Less frequently, anaphylactic reactions, coma, vomiting, blurred vision, drowsiness, sweating, insomnia, headache and tachycardia have been reported. Refer SmPC for complete details.

Pack size and UK list price: Nefopam hydrochloride 60 mg film-coated tablets (PL 25298/0316) pack size: 90's, £19.90

Legal category: POM

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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 Brown & Burk via email to pv@bbukltd.com or via phone on +44 (0)203 384 7188