

Prescribing Information

Dipipanone 10mg and Cyclizine 30mg Tablets (dipipanone hydrochloride and cyclizine hydrochloride)

Presentation: Each tablet contains 10mg dipipanone hydrochloride and 30mg cyclizine hydrochloride.

Indication: For the management of moderate to severe pain in medical and surgical conditions in which morphine may be indicated. Cyclizine is effective in preventing nausea and vomiting associated with the administration of narcotic analgesics.

Dosage and administration: For oral use.

Adults: An initial dose of one tablet every 6 hours can be given which can be increased by half tablet every half hour in severe intractable pain. The dose should not exceed 12 tablets in 24 hours.

Elderly: There is no specific information on the use in elderly patients.

Children: Rarely indicated in children and dosage guidelines cannot be stated.

Contraindications: Hypersensitivity to dipipanone or cyclizine, respiratory depression (especially in the presence of cyanosis and excessive bronchial secretions), bronchial asthma, acute alcoholism, head injury and raised intracranial pressure, patients receiving current or recent treatment with MAOIs, ulcerative colitis, severe hepatic impairment, severe renal impairment and during spasm of the biliary and renal tracts.

Precautions and warnings: Repeated use may lead to tolerance and physical/ psychological dependence. Extreme caution must be taken in the presence of hypothyroidism, adrenocortical insufficiency, prostatic hypertrophy, hypotension secondary to hypovolaemic shock, diabetes mellitus, phaeochromocytoma.

Interactions: Phenothiazine drugs, alcohol, sedatives, tricyclic antidepressants, anticholinergic agents and dexamphetamine.

Pregnancy and lactation: Not recommended during pregnancy and lactation.

Undesirable effects: Respiratory depression, mental clouding, drowsiness, sedation, confusion, mood changes, euphoria, dysphoria, psychosis, restlessness, miosis, raised intracranial pressure, constipation, nausea, vomiting, sweating, facial flushing, hypotension, urticarial, rashes; difficulty with micturition; biliary and renal tract spasm, vertigo, dryness of the mouth/nose/throat, blurred vision, tachycardia, urinary retention, restlessness, nervousness, insomnia, and auditory/visual hallucinations.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: The signs of overdosage include respiratory depression, pin-point pupils, hypotension, circulatory failure and deepening coma. Mydriasis may replace miosis as asphyxia intervenes. Drowsiness, floppiness, miosis and apnoea have been reported in children, as have convulsions. General supportive measures should be employed as required. Patients should be monitored closely for at least 48 hours after recovery in case of relapse, since the duration of action of the antagonist may be substantially shorter than that of dipipanone.

Legal category: POM

Basic NHS cost: £129.74 for 50 tablets.

Marketing Authorisation Number: PL 20072/0009

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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Adverse events should be reported to the local regulatory authority.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to **Amdipharm Mercury Medical Information** at **08700 70 30 33**

or via e-mail to medicalinformation@amcolimited.com