Milam®

Midazolam film coated tablet

DESCRIPTION

Milam is a preparation of midazolam maleate, a benzodiazepine derivative. It is used as a premedicant and sedative in surgical and other procedures and for the indication of anaesthesia. It is a rapidly acting hypnotic with a short biological half-life. Midazolam reduces sleep onset time and prolongs sleep without quantitatively impairing REM sleep, waking phases are reduced and sleep efficiency is improved. It has also anticonvulsant, anxiolytic and muscle-relaxant properties.

INDICATIONS

- Sedation with amnesia.
- Sedation in premedication and induction of anaesthesia before surgical or diagnostic procedures.
- Short-term treatment of sleep disturbances having clinically significant severity.
- Disturbances of sleep pattern, difficulty in getting to sleep and difficulty in getting back to sleep after premature waking.

DOSAGE AND ADMINISTRATION

Standard: For adults 7.5 mg to 15 mg daily.

Special instructions: For elderly or frail patients 7.5 mg daily. It is also suitable for patients with mild impairment of liver and/ or renal function.

CONTRAINDICATIONS

- Hypersensitivity to midazolam or other benzodiazepines.
- Patients with a history of alcohol and / or drug abuse or dependency.
- Severe respiratory depression.
- Acute pulmonary insufficiency.
- Sleep apnea syndrome.
- Severe hepatic impairment.
- Myasthenia gravis.

PRECAUTIONS

Where treatment is given concomitantly with CNS depressant medications or in general with substances such as erythromycin, azole-type antimycotics and cimetidine that interfere with the metabolism of midazolam by cytochrome P-450 3 A, cautions should be taken. Administration of Milam concomitantly with other centrally acting

medications should be avoided and patients should be warned against simultaneous consumption of alcohol, because combination can potentiate the undesirable effects of both substances. All anxiolytics and hypnotics can precipitate coma. So it should be avoided in case of severe hepatic impairment. As with all hypnotics, sedatives and tranquilizers, prolonged treatment can lead to drug dependence in predisposed patients. Drowsiness may affect performance skilled tasks (e.g. driving).

SIDE-EFFECTS

Tiredness, drowsiness, muscle weakness, confusion, ataxia (especially in the elderly) and amnesia. These effects occur predominantly at the start of treatment and generally disappear with dose reduction or continuation of therapy. Respiratory depression and respiratory arrest reported, particularly with high doses.

USE IN PREGNANCY & LACTATION

There is clear evidence that the use of benzodiazepines during pregnancy endangers the human fetus. Therefore Milam should not be taken during pregnancy, especially the first trimester, unless there is a compelling indication for its use and no safer therapeutic alternative is available. Midazolam is excreted in breast milk and can cause drowsiness and poor feeding in the infant. Therefore, Milam should not be taken by nursing mothers.

PHARMACEUTICAL PRECAUTION

Keep away from light, store in a dry place. Keep out of reach of children.

PACKAGING

Milam 7.5 mg tablet: Box containing 4 strips of 10 tablets each. Each film coated tablet contains midazolam maleate equivalent to midazolam BP 7.5 mg.

Milam 15 mg tablet: Box containing 2 strips of 10 tablets each. Each film coated tablet contains midazolam maleate equivalent to midazolam BP 15 mg.

SK+F
Manufactured by
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