

# Midazolam Injection USP

**5mg/ml** For IV / IM Use.

## COMPOSITION:

Each ml Contains:  
Midazolam USP (As hydrochloride) ..... 5mg  
Benzyl Alcohol (As preservative) ..... 1%v/v  
Water for Injection BP ..... q.s.

## CATEGORY:

Benzodiazepine.

## GENERAL INFORMATION:

Midazolam is a new, short acting benzodiazepine with sedative properties, twice as potent as diazepam. It is also used as an anaesthetic inducing agent.

## PHARMACOKINETICS:

It is rapidly absorbed following intra muscular administration with more than 90% bio availability.  
On Set of Action: I.M: 15 minutes; I.V.: 1.5-5 minutes.  
Duration of Action: 2-6 hours.

## INDICATIONS:

For pre-operative sedation, conscious sedation prior to short diagnostic or endoscopic procedures, induction of general anaesthesia prior to administration of other anaesthetic agents.

## DOSAGE & ADMINISTRATION:

Adults: Pre-operative sedation: 0.07-0.08 mg/kg, 1 hour before surgery intra-muscularly in patients below 60 years.  
Conscious sedation: 1mg/ml I.V. dose titrated slowly. Avoid rapid or single bolus I.V.administration. Maintenance dose may be given in increments of 25% of the dose used to first reach the sedatives endpoint, by slow titration.  
Induction of anaesthesia: Unpremedicated patients: Initial dose of 0.3-0.35 mg/kg, administered over 20-30 seconds in an adult below 55 years. If needed increments of 25% of patient's initial dose may be used.  
Premedicated patients: When the patient has received sedative or narcotic premedication the recommended dose is 0.15-0.35 mg/kg. An initial dose of 0.2 mg/kg is recommended for surgical patients over 55 years.

## CONTRAINDICATIONS:

Known hypersensitivity to benzodiazepines, patients with narrow angle glaucoma.

## ADVERSE EFFECTS:

Local effects like redness and phlebitis, apnoea (usually seen on I.V. administration). Rarely nausea, vomiting, headache, drowsiness, hiccups and retrograde amnesia may occur.

## WARNINGS/ PRECAUTIONS:

Patients should not operate motor vehicles or hazardous machinery, impaired renal function patients. Concomitant administration of alcohol, barbiturates and other CNS depressants should be avoided.

Midazolam should be used with caution in patients with heart, kidney, liver or lungs diseases, in narrow angle glaucoma. It should be used with caution in elderly patients.

## INTERACTIONS:

Anaesthetics (inhalation): Inhalational anaesthetics may need to be reduced if midazolam is used as induction agent I.V.

Azole antifungal agents: Enhanced CNS depression and prolonged effects.

CNS depressants: May increase risk of hypoventilation and contribute to prolonged effect.

Ethanol: Increased CNS effects with acute ethanol ingestion.

Oral contraceptives: May result in prolongation of midazolam half life.

Rifamycin: Increase in midazolam & metabolite clearance & decrease in elimination half life.

Theophylline: Sedative effect of midazolam may be antagonised.

Thiopental: A reduction in induction dosage requirement of thiopental.

Verapamil: May produce increased CNS depression and prolonged effects.

## STORAGE:

Store between 15°C to 30°C.

## PRESENTATION:

10 ml vial in mono carton packed.

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Manufactured in India:

