

# anOuil

Tablet/Injection

(Midazolam)

## Presentation

**Anquil 7.5 Tablet** : Each film coated tablet contains Midazolam Maleate INN equivalent to Midazolam 7.5 mg.

**Anquil 15 Tablet** : Each film coated tablet contains Midazolam Maleate INN equivalent to Midazolam 15 mg.

**Anquil 15 IM/IV Injection** : Each ampoule contains 3 ml sterile solution of Midazolam USP 15 mg (as Midazolam Hydrochloride) for IM / IV injection.

## Indications

Disturbances of sleep rhythm and all forms of insomnia particularly difficulty in falling asleep either initially or after premature awakening. Sedation in premedication before surgical or diagnostic procedures.

Midazolam is used before operations or procedures to relax patient, make a patient sleepy and to decrease memory of the event. This drug may also be used to treat seizures.

## Dosage and Administration

### Tablet:-

*Standard dosage:* The usual adult dose is 7.5-15 mg.

*Special dosage instructions:* In elderly and debilitated patients, the recommended dose is 7.5 mg. This dosage applies also to patients with impaired liver and kidney function.

In premedication, 15 mg of Midazolam should be given orally 30 to 60 minutes before the operation, unless the parenteral route is preferred.

### Injection:-

*Endoscopic or Cardiovascular procedures:*

*Adult:* initial dose is 2.5 mg (IV)

*Elderly & debilitated patients:* 1-1.5 mg (IV)

*Induction of Anesthesia:* Adult: 10-15 mg (IV) or 0.07-0.1 mg/Kg body weight, usually 5 mg (IM)

*Children:* 0.15-0.20 mg/Kg (IM)

*Elderly & debilitated patients:* 0.025-0.05 mg/Kg (IM)

*Rectal administration in children:* for preoperative sedation, rectal administration of the ampoule solution is 0.35-0.45 mg/Kg, 20-30 minutes before induction of general anesthesia

## Contraindications

- Known hypersensitivity to benzodiazepines or any of the ingredients.
- Severe or acute respiratory insufficiency/depression.
- Severe hepatic insufficiency.

## Side Effects

Side-effects are usually mild.

Dizziness, headache and pain or redness at the injection site might occur. Have to report promptly if unusually slow or shallow breathing occurs. Very unlikely but report promptly: unusually fast/slow/irregular heartbeat, fainting, confusion, mental/mood changes, trouble breathing, muscle twitching, uncontrolled movements. Immediate medical attention is necessary if an allergic reaction occurs, however unlikely. Symptoms include: throat discomfort, difficulty breathing, skin rash, hives, itching.

## Precautions

Precautions should be taken in care of allergies (especially drug allergies), heart problems, kidney problems, liver problems, lung diseases, narrow-angle glaucoma. Alcohol should be avoided while using this drug. Side effects may be aggravated. Should not drive or use hazardous machinery until the effects of the drug have disappeared (e.g., drowsiness). A preservative (benzyl alcohol) which may be found in this product or in the liquid used to mix this product (diluent) can infrequently cause serious problems (sometimes death), if given in large amounts (more than 100 mg/kg daily) to an infant during the first months of life (neonatal period). The risk is also greater with low birth weight infants. Symptoms include sudden gasping, low blood pressure, or a very slow heartbeat. If possible, a preservative-free product should be used when treating neonates. Caution is advised when this drug is used in the elderly as elderly patients are usually more sensitive to its effects.

## Drug Interactions

Patient will ask doctor about all nonprescription and prescription medication he/she use, especially of: H<sub>2</sub> blockers (e.g., cimetidine), fluconazole, theophylline, aminophylline, erythromycin. Few drugs can make drowsy, such as: narcotic pain relievers (e.g., morphine, codeine), psychiatric medicines, other anti-anxiety drugs, anti-seizure drugs, certain antihistamines (e.g., diphenhydramine), other muscle relaxants, sleeping pills, sedatives.

## Use in Pregnancy and Lactation

This drug is not recommended for use during pregnancy. Have to consult with doctor before using this drug. This drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Have to consult with doctor before breast-feeding.

## Overdose

Symptoms of overdose may include confusion, slow reflexes, clumsiness, deep sleep, and loss of consciousness. Immediate consultation is necessary in case of serious poisoning.

## Storage Conditions

Store in a cool and dry place, away from light. Keep out of reach of children.

## Commercial Pack

**Anquil 7.5 Tablet** : Each box contains 3 blister packs of 10 tablets.

**Anquil 15 Tablet** : Each box contains 1 blister pack of 10 tablets.

**Anquil 15 IM/IV Injection:** Each box contains 1 blister pack of 1 ampoule of 3 ml sterile solution and 1 sterile disposable syringe.

Manufactured by:



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