

# STESOLID

## Diazepam

### Therapeutic group

Anxiolyticum and anticonvulsant

### Composition

Rectal tubes of 2.5 ml containing 5 and 10 mg of diazepam in solution.

Also contains benzoic acid, sodium benzoate, ethanol, propylene glycol, benzyl alcohol.

### Pharmacology

Diazepam has an anxiolytic, sedative, amnesic, hypnotic, anti convulsant, and muscle-relaxing activity.

Diazepam is easily absorbed from the rectal mucosa. The effects is already seen within 5-10 minutes. Maximal plasma concentration is attained within 10-20 minutes.

Diazepam is metabolised in the liver and its major metabolite, desmethyldiazepam, is pharmacologically active. The half life of diazepam is within a range of 20 hours to a few days; that of desmethyldiazepam is longer. Diazepam is distributed throughout the body and passes quickly the blood-brain barrier. In the blood 96-98 per cent of diazepam is bound to plasma proteins.

### Indications

Stesolid rectal tubes are particularly well suited in the treatment of convulsion, including febrile convulsions in children, where the rapid onset of action is imperative.

### Contraindications

Myasthenia gravis

### Pregnancy/lactation

Should not be used

### Side effects

The side effects are dose-related and are generally mild and rare. The commonest is drowsiness. Less common are dizziness, difficulties with concentration, and ataxia. Elderly patients are especially susceptible to these side effects. Paradoxical reactions, such as excitation, aggressiveness and hallucinations are rarely seen. Confusion may occur in elderly patients taking high doses.

### Dosage

Adult: 10 - 20 mg  
Children 6 - 12 years of age: 10 mg  
1 - 5 years of age : 5 mg

The dosage may be repeated if necessary.

### Interactions

Disulfiram, cimetidine and omeprazole increases the effect of diazepam. Rifampicin increases the clearance of diazepam. Premedication with diazepam prolongs sleep after ketamine. Theophylline counteracts the effect of diazepam. The sedative action of diazepam is intensified by alcohol, hypnotics, neuroleptics, antihistamines, morphines and its analogues.

### Warning and precautions

Diazepam may increase the patient's reaction time and therefore, driving vehicles or operating machinery should be avoided. Care should be exercised in using diazepam in patients with reduced kidney or liver function. Elderly patients are more susceptible to the effects of diazepam and need lower doses.

Treatment with large doses over a long period carries the risk of increased tolerance and habituation.

Abrupt discontinuation may cause withdrawal symptoms, which appear up to 10 days thereafter.

### Overdose

Overdosage brings about hypotension, respiratory depression, and coma.

Flumazenil may be used as antidote to poisoning. The treatment is symptomatic artificial respiration may be necessary.



1. Remove top by turning it carefully 2-3 times without pulling.



2. Put the patient on the stomach or side with a cushion under the hip. A small child can lie across your knees.

## AAAM4006 - Diazepam 5 mg -, PIL, Singapore

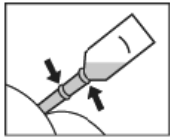
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Origination Date: 02.09.2020	Manuf. site: Actavis Jakarta	Resent Date:	2.
Originated by: KM	Min pt size*: 9pt	Approval Date:	3.
Revision Date: 19.10.2020	SAP Code:	NON-PRINTING COLOURS	4.
Revised by: KM			5.
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**teva**

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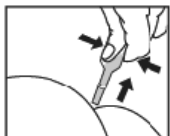
3. Insert the nozzle into the anus, but only to the first mark for children 1-3 years old



4. Always keep the tube angled with nozzle downwards during administration. Like this NOTE: Do not squeeze the tube before it has been inserted.



5. When inserted, empty the tube by pressing with your thumb and index finger.



6. Keep pressing while withdrawing the tube. Hold the buttocks together for a few moments to prevent seepage.



7. The small amount left in the tube will not affect the correct dose.

#### Storage

Store at room temperature below 25°C, away from light.

Stesolid 5 mg/2.5 ml Rectal Tube :

Available in box of 5 rectal tubes.

Stesolid 10 mg/2.5 ml Rectal Tube :

Available in box of 5 rectal tubes.

Not all pack sizes are available

**ON MEDICAL PRESCRIPTION ONLY**

Date of revision of package insert : August 2020

#### Manufactured by

PT Actavis Indonesia, Jakarta, Indonesia

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AAAM4006

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