

STESOLID[®] Rectal Tubes: DATA SHEET

NAME OF MEDICINE

STESOLID[®] rectal tube
Diazepam 5mg in 2.5ml and 10mg in 2.5ml solution.

PRESENTATION

Stesolid[®] is a clear colourless-to-slightly-yellowish aqueous liquid, in a yellow polyethylene tube.

Stesolid[®] is available in a 5mg/2.5ml tube and 10mg/2.5ml tube, for rectal administration.

USES

PHARMACOLOGICAL ACTIONS

Diazepam has anxiolytic, sedative, amnestic, hypnotic, anticonvulsant and muscle-relaxing activity.

Diazepam acts centrally. As a benzodiazepine, it facilitates GABA-mediated synaptic inhibition. It is bound in the brain to specific benzodiazepine-receptors, which are found particularly in the limbic system, amygdaloid nucleus and the frontal cortex.

PHARMACOKINETICS

Absorption: diazepam is quickly absorbed from the rectal mucosa. The maximum serum concentration is reached within 17 minutes. Absorption by this route is 100%, and is therefore comparable in extent to an intravenous injection of diazepam formulated for IV injection. .

Diazepam is distributed systemically. In the blood it is 96-98 per cent bound to plasma protein. It quickly passes the blood-brain barrier. It crosses the placenta and passes into breast milk.

Diazepam is metabolised in the liver and its major metabolite, desmethyldiazepam, is pharmacologically active. The metabolites are excreted in the urine as glucuronide or sulphate. A very small amount is excreted via the bile.

The plasma half-life of diazepam varies from person to person, and increases with age. The mean is about 50 hours. The half-life of desmethyldiazepam is about 100 hours.

INDICATIONS

For the treatment of febrile and childhood convulsions, where rapid onset of anticonvulsant activity is imperative.

DOSAGE AND ADMINISTRATION

For rectal administration only

AGE GROUP	Dosage in mg	Number of 5mg/2.5mL tubes	OR	Number of 10mg/2.5mL tubes
Adults	10-20mg	2-4		1-2
Children(7-12 years):	10mg	2		1
Children(1-6 years)	5mg	1		Not applicable

If necessary, these doses may be repeated once only, after five minutes

A maximum dose of 30 mg is recommended, unless adequate medical supervision and monitoring are available.

Administration

For rectal administration:

1. Position the patient with the buttocks raised. If a child, place the child across your knee.
2. Remove the tube cap and coat the opening of the nozzle with a little Vaseline.
3. Insert the *entire* length of the nozzle (about 5cm) into the anus.
In children less than three years of age, insert the nozzle *half-way* only.
4. **IMPORTANT:** In order to empty the tube, the nozzle must point downwards.
5. When the tube feels empty, keep squeezing it, while simultaneously withdrawing the nozzle.
6. Keep the patient in the same position and press the buttocks together for a few minutes, to avoid seepage.

CONTRA-INDICATIONS

Hypersensitivity to diazepam or to benzodiazepines, or to any of the excipients listed later in this data sheet.

Myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome, severe hepatic insufficiency.

Not for IV, IM or oral administration.

WARNINGS AND PRECAUTIONS

May impair driving and operating machinery.

Benzodiazepines can cause blurred vision/dizziness and impair concentration.

Benzodiazepines can cause dependency, even in short-term use. Any course of treatment should be as brief as possible.

After chronic use, tolerance will occur. For withdrawal of benzodiazepines, doses should be tapered off gradually, according to clinical response. Rebound insomnia and anxiety may occur especially after abrupt discontinuation of treatment.

Benzodiazepines should be used with extreme caution in patients with a history of alcohol or drug abuse.

Benzodiazepines should not be used alone to treat depression or anxiety associated with depression (suicide may be precipitated in such patients).

Pregnancy and Lactation:

Although there is no evidence that it induces teratogenic injury, diazepam, like other medications, should preferably not be used during pregnancy, especially during the first and last trimesters unless the benefit is considered to outweigh the potential risk.

Since benzodiazepines are found in breast milk, benzodiazepines should not be given to breast feeding mothers.

ADVERSE EFFECTS

The side effects of diazepam are usually mild and infrequent. The most common side-effects are drowsiness, light-headedness, unsteadiness and ataxia.

Paradoxical reactions to benzodiazepines, provoking excitement instead of sedation, have been reported.

In rare cases, after large doses of diazepam, depressed respiration, fall in blood pressure, ataxia and dysarthria have been described.

INTERACTIONS

Diazepam, as a benzodiazepine, enhances the central depressive effects of other CNS – active agents, for example: alcohol, narcotic analgesics, anaesthetics, anti-epilepsy compounds, hypnotics, anxiolytics/sedatives, antidepressant agents and sedative antihistamines.

Compounds that inhibit certain hepatic enzymes (particularly cytochrome P450) may enhance the activity of benzodiazepines.

OVERDOSAGE

Overdose of benzodiazepines usually presents as some degree of central nervous system depression, ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion and lethargy; in more severe cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death.

Overdose of diazepam should not present a threat to life unless administered to a recipient affected by CNS depressants, including alcohol.

Emergency management of overdose: Gastric lavage and adequate airway maintenance may be necessary. Otherwise, management is symptomatic. Intravenous fluids may be administered and flumazenil may be useful as an antidote.

EXCIPIENTS

Benzoic acid, ethanol, propylene glycol, sodium benzoate, benzyl alcohol, purified water.

PHARMACEUTICAL PRECAUTIONS

Store in a cool place below 25°C and away from light.

MEDICINE CLASSIFICATION

Prescription Medicine.

CONTROLLED DRUG C5.

PACKAGE QUANTITIES

Boxes of five rectal tubes.

FURTHER INFORMATION

Nil

NAME AND ADDRESS

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Under licence from:
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