

For the use only of a Registered medical practitioner or a hospital or a laboratory.

NOTIUM

DIAZEPAM INJECTION BP 10 mg/2 ml

Qualitative & Quantitative Composition:

Each ml contains:
Diazepam BP 5 mg
Benzyl Alcohol BP 1.5 %v/v
Water for Injections BP q.s

Pharmaceutical Form:

Injection

Clinical Particulars

Therapeutic Indications:

Diazepam Injection is indicated:
Treatment of anxiety and tension states in various psycho-reactive disorders. As anti-convulsant in the control of status epilepticus. As adjunctive therapy for the relief of skeletal muscle spasm or tetanus. As an adjuvant in pre-medication before surgery or in the control of alcohol withdrawal syndrome. Diazepam is only indicated when the disorder is severe, disabling or subjecting the individual to extreme stress.

POSODOGY AND METHOD OF ADMINISTRATION:

Adults:

Severe acute anxiety or agitation:
10 mg IV or IM Injection which may be repeated after an interval of not less than 4 hours.

Delirium Tremens:

10-20 mg IV or IM Higher doses may be needed depending on severity of symptoms.

Acute Muscle Spasm:

10 mg IV or IM Injection which may be repeated after an interval of not less than 4 hours.

Tetanus:

Initially an IV dose of 0.1-0.3 mg/kg body weight, repeated at intervals of 14 hours. Continuous IV infusion of 3-10 mg/kg body weight per 24 hours can also be used. The chosen dose should be related to the severity of the case and in extremely severe cases higher doses have been used.

Status epilepticus, convulsions due to poisoning:

10-20 mg IV or IM, repeated if necessary 30-60 minutes later. If indicated, this may be followed by slow intravenous infusion (maximum dose 3 mg/kg body weight over 24 hours)

Pre-operative medication or premedication:

0.2 mg/kg body weight. The usual adult dose is 10-20 mg but higher doses may be necessary according to the clinical response.

Elderly or Debilitated Patients:

Doses should not exceed half those normally recommended.

Children:

Status epilepticus, convulsions due to poisoning, febrile convulsions:
0.2-0.3 mg/kg body weight IV (or IM) or 1 mg per year of life.

Tetanus:

As for adults.

Pre-operative medication or premedication:

0.2 mg/kg body weight. The Injection should be given slowly (0.5 ml per minute). Diazepam Injection should be given into a large vein of the antecubital fossa, the patient in a supine position throughout the procedure to reduce the possibility of hypotension or apnoea occurring.

Method of administration

Diazepam Injection BP may be given IV, IM or by IV infusion.

Contraindications:

Diazepam Injection is contraindicated in the following group of patients:
Known hypersensitivity to Diazepam or any other benzodiazepine. Severe chronic obstructive pulmonary disease. Acute glaucoma
Myasthenia gravis
Hypoalbuminemia

Neonates

Diazepam should be avoided in patients with pre-existing central nervous system depression or coma, acute pulmonary insufficiency or sleep apnoea.

Special warnings and precautions for use:

Warnings:

Special precautions should be exercised with the elderly patients as parenteral administration of Diazepam is more likely to cause apnoea, hypotension, bradycardia or cardiac arrest in geriatric patients. Diazepam induced disinhibition may precipitate suicide or aggressive behaviour so it should be used with care in patients with personality disorders, mental depression or suicidal tendencies. Caution should be exercised in patients with impaired hepatic and/or renal functions.

Precautions:

Diazepam is not recommended for the primary treatment of psychotic illness. It should not be used alone to treat depression or anxiety with depression (suicide may be precipitated in such patients). It should be used with extreme caution in patients with history of alcohol or drug abuse.

General

Patients sensitive to any of the benzodiazepines may also be sensitive to Diazepam, so it should be used with caution in such patients. Diazepam Injection should not be mixed or diluted with other solutions or IV fluids because the resulting admixtures are unstable.

Paediatric use

Children, especially the very young, are usually more sensitive to the central nervous system effects of benzodiazepines. Prolonged central nervous system depression may be produced in neonates because of inability to biotransform Diazepam into inactive metabolites.

Dependence

There is a potential for abuse and the development of physical and psychic dependence, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases the following symptoms may occur: Derealisation, depersonalisation, hyperacusis, numbness and tingling of extremities, hypersensitivity to light, noise, raise and physical contact, hallucinations or epileptic seizures.

Size : 110 X 200 mm (Front)