Sedil®

Diazepam Anxiolytic

COMPOSITION

Sedil® Tablet : Each tablet contains Diazepam BP 5 mg.

Sedil® Injection : Each ml injection contains Diazepam BP 5 mg.

PHARMACOLOGY

Sedil® (diazepam) is a benzodiazepine tranquilizer with anticonvulsant, sedative, muscle relaxant and amnesic properties. It is used in the treatment of anxiety and tension states and also as premedicant in the control of muscle spasm. Diazepam induces calming effect by acting on parts of the limbic system, the thalamus and hypothalamus. Diazepam is one of the most rapidly and completely absorbed benzodiazepines, reaching peak concentrations in about an hour in adults, but as quickly as 15 to 30 minutes in children. Secondary peaks in the plasma concentration have been described for diazepam at 6 to 12 hours after an oral dose. This is most likely due to enterohepatic recirculation. Diazepam is bound to plasma protein to a great extent (98.5%).

After intravenous administration of diazepam, it is redistributed in a manner typical of that for highly lipid soluble agents. Central effects develop promptly but wane rapidly as the drugs move to other tissue. Diazepam is extensively metabolized in the liver. It is excreted in the urine, mainly in the form of its metabolites, either free or in conjugated form. There is no biliary excretion.

INDICATION

Sedil® is mainly used for the treatment of anxiety, which may be the result of many factors e.g. transient situational problems, acute and chronic stress of life, chronic medical problems, intractable pain exacerbated by apprehension and depression etc. For skeletal muscle spasm due to reflex spasm to local pathology, Sedil® is indicated as an adjunct to relieve the symptoms.

In patients who are to undergo surgical measures, Sedil® is a useful premedication (I.M. route recommended) for relief of anxiety and tension.

DOSAGE AND ADMINISTRATION

Adults :

Indication	Route	Dosage
Severe anxiety states	Oral	15 to 30 mg daily in divided doses.
	I.V. or I.M.	10 mg repeated after 4 hours.
Status epilepticus	I.V.	5 to 10 mg as required. This may be repeated at intervals of 10 to 15 minutes up to a maximal dose of 30 mg. If necessary, this regimen can be repeated in 2 to 4 hours, but no more than 100 mg should be administered in 24 hours period.
Anaesthesia	I.V.	0.6 mg/kg
Tetanus	I.V.	2 to 20 mg at intervals of 2 to 8 hours.
Minor surgical procedure and dentistry	I.M.	10 to 30 mg adjusted to patients requirement.
Strychnine poisoning	I.V.	10 mg. Smaller doses for children.
Mild anxiety states	Oral	5 mg twice daily or 2 mg thrice daily.
Cerebral palsy	Oral	Up to 60 mg.
Muscle Spasm	Oral	2 to 15 mg daily in divided doses.
	I.V. or I.M.	10 mg repeated after 4 hours.

Children :

Status epileptius, convulsions due to poisoning, febrile convulsions	0.2 to 0.3 mg/kg body weight IV (or IM) or 1 mg per year of life
Tetanus	As for adults dose
Pre-operative medication	0.2 mg/kg body weight

CONTRAINDICATION AND PRECAUTION

Sedil® is contraindicated in patients with known history of hypersensitivity to it. Porphyria or a family history of porphyria contraindicates the use of Sedil®. It is also contraindicated in patients with acute narrow angle glaucoma and open angle glaucoma unless concomitant appropriate therapy is given. Head injury also contraindicates the use of diazepam.

Caution should be observed when giving Sedil® to elderly or debilitated patients who are liable to be sensitive to its side effects; to patients with real or hepatic dysfunctions. Extreme care should be taken in administering injectable Sedil® particularly by the I.V. route to the elderly patients to very ill patients and to those with limited pulmonary reserve because of the possibility of apnea and/or cardiac arrest. Barbiturates, alcohol and other central nervous system depressants will increase the risk of apnea if given concomitantly. Injectable Sedil® should be administered to patients in shock, coma, or in acute alcohol intoxication.

SIDE EFFECT

The side effects of Sedil® are infrequent and mild. Drowsiness, light headedness, slight ataxia, vertigo, dry mouth, inattentiveness may occur and are dose dependent. Other effects that may be observed rarely include hypotension, gastro-intestinal and visual disturbances. In case of long term medication change in libido may occur.

DRUG INTERACTION

If diazepam is given concomitantly with centrally acting drugs such as neuroleptics, tranquillisers, antidepressants, hypnotics, analgesics and anaesthetics, the sedative effects are likely to be intensified.

Known inhibitors of hepatic enzymes e.g. cimetidine and omeprazole have been shown to reduce the clearance of diazepam and may potentiate their action and known inducers of hepatic enzyme, e.g. rifampicin may increase the clearance of diazepam.

USE IN PREGNANCY AND LACTATION

The use of Sedil® during the first trimester of pregnancy should almost always be avoided as it bears a risk of congenital malformation.

Diazepam has been detected in breast milk. If possible the use of diazepam should be avoided during lactation.

HOW SUPPLIED

Sedil® Tablet : Box containing 25 x 20 tablets in blister pack.

Sedil® Injection : Box containing 2 x 5 ampoules in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH