Epam®

Nitrazepam

Description
Nitrazepam (**Epam**®) is a benzodiazepine hypnotic. It has useful sedative properties, allaying anxiety and inducing sleep. It is an intermediate acting benzodiazepine. It is used as a hypnotic in the short-term management of insomnia.

Composition
Epam® Tablet: Each tablet contains Nitrazepam BP 5 mg.

Mode of action
Nitrazepam binds with benzodiazepine receptors and potentiates the actions of gamma-aminobutyric acid (GABA) in the spinal cord, brain stem, cerebellum, limbic system and cerebral cortex.

Pharmacokinetics
The drug is well absorbed from the GI tract with peak blood levels being achieved within 2 hours of administration. Two hours after administration, the concentration of nitrazepam in the cerebrospinal fluid is about 8% and after 36 hours approximately 16% of the concentration is found in the plasma. The half-life is, on average, 24 hours. Steady-state levels are achieved within 5 days. Nitrazepam undergoes bio-transformation to a number of metabolites, none of which possesses significant clinical activity. About 5% is excreted unchanged in the urine together with less than 10% each of the 7-amino and 7-acetylamino metabolites in the first 48 hours. In younger persons, the volume of distribution is 2 L/kg.

Indications
Short-term treatment of insomnia when it is severe, disabling or subjecting the individual to unacceptable distress, where daytime sedation is acceptable. An underlying cause for insomnia should be sought before deciding upon the use of benzodiazepines for symptomatic relief.

Dosage & administration
Adults: 5 mg before retiring. This dose may, if necessary, be increased to 10 mg.
Elderly or debilitated patients: The elderly or patients with impaired renal and/or hepatic function will be particularly susceptible to the adverse effects of nitrazepam. Doses should not exceed half of those normally recommended. In patients with chronic pulmonary insufficiency and in patients with chronic renal or hepatic disease, dosage may need to be reduced. Dosage should be adjusted on an individual basis. Treatment should, if possible, be on an intermittent basis and should be started with the lowest recommended dose. Generally, the duration of treatment varies from a few days to two weeks with a maximum of four weeks. Nitrazepam should be taken just before going to bed.

Side effects
The adverse effects of nitrazepam are usually mild and include nausea, constipation, and slurred speech. Patients may experience drowsiness, lightheadedness and a feeling of 'hang over' in the next day.

Contraindications
Patients with known sensitivity to benzodiazepines and any of the excipients; acute pulmonary insufficiency; respiratory depression; phobic or obsessional states; chronic psychosis; myasthenia gravis; sleep apnea syndrome; severe hepatic insufficiency; use in children.

Use in pregnancy & lactation
It is better to avoid nitrazepam in pregnancy and lactation if not absolutely needed.

Precautions
Nitrazepam should not be used alone to treat depression or anxiety associated with depression, since suicide may be precipitated in such patients. Benzodiazepines should be used with extreme caution in patients with a history of alcohol or drug abuse. Some loss of efficacy to the hypnotic effects of short-acting benzodiazepines may develop after repeated use for a few weeks. Extreme caution should therefore be used in prescribing benzodiazepines to patients with personality disorders. If any of these reactions occur, use of the drug should be discontinued. These reactions may be quite severe and are more likely to occur in the elderly.

Drug interactions
Enhancement of the central depressive effect may occur if benzodiazepines are combined with centrally acting drugs such as neuroleptics, tranquillizers, antidepressants, hypnotics, analgesic and anesthetics, antiepileptics and sedative antihistamines. In case of narcotic analgesics, enhancement of the euphoria may also occur leading to an increase in psychological dependence. When nitrazepam is used in conjunction with antiepileptic drugs, side effects and toxicity may be more evident. The sedative effect may be enhanced when the product is used in combination with alcohol.

Overdosage
When taken alone in overdosage, nitrazepam presents few problems in the management and should not present a threat to life unless combined with other CNS depressants (including alcohol). Following overdose with oral benzodiazepines, vomiting should be induced (within one hour) if the patient is conscious or gastric lavage undertaken with the airway protected if the patient is unconscious. If there is no advantage in emptying the stomach, activated charcoal should be given to reduce absorption. Special attention should be paid to respiratory and cardiovascular functions in intensive care. Overdosage of benzodiazepines is usually manifested by degrees of CNS depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion, dysarthria and lethargy; in more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death.

Storage
Store in a cool (Below 25° C temperature) and dry place protected from light.

Packaging
Epam® Tablet: Each carton contains 20X10 tablets in blister pack.

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