PSICODEX 5®

Forms and Presentation

Psicodex 5®: Box of 30 tablets.

Composition

Psicodex 5®: Each tablet contains 5 mg Chlordiazepoxide HCL

Indications.

Psicodex 5® is indicated for the management of anxiety disorders or for the short-term relief of symptoms of anxiety , withdrawal symptoms of acute alcoholism , and preoperative apprehension and anxiety . Anxiety and tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

The effectiveness of this medication in long-term , that is , more than 4 months , has not been assessed by systematic clinical studies . The physician should periodically reassess the usefulness of the drug for the individual patient.

Dosage and Administration

Because of the wide range of clinical indications for Psicodex 5 , the optimum dosage varies with the diagnosis and response of the individual patient . The dosage, therefore , should be individualized for maximum beneficial effects.

ADULTS (Usual Daily Dose):

- *Relief of Mild and Moderate Anxiety Disorders and Symptoms of Anxiety :* 5 mg to 10 mg , 3 or 4 times daily.
- *Relief of severe Anxiety Disorders and Symptoms of Anxiety:* 20 mg or 25 mg, 3 or 4 times daily.
  Geriatric Patients, or in the presence of debilitating disease: 5 mg 2 to 4 times daily.
- Preoperative Apprehension and Anxiety on Day preceding surgery, 5 to 10 mg orally, 3 or 4 times daily.

PEDIATRIC PATIENTS (Usual Daily Dose):

Because of the varied response of pediatric patients to CNS - acting drugs, therapy should be initiated with the lowest dose and increased as required : 5 mg, 2 to 4 times daily (may be increased in some pediatric patients to 10 mg, 2 to 3 times daily.)

Since clinical experience in pediatric patients under 6 years of age is limited, the use of the drug in this age group is not recommended .

For the relief of withdrawal symptoms of acute alcoholism, the parenteral form is usually used initially. If the drug is administered orally , the suggested initial dose is 50 to 100 mg , to be followed by repeated doses as needed until agitation is controlled - up to 300 mg per day. Dosage should then be reduced to maintenance levels.

Contraindications

Psicodex 5® is contraindicated in patients with known hypersensitivity to the drug.

Warnings and Precautions.

Chlordiazepoxide HCL may impair the mental and / or physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery . Similarly , it may impair mental alertness in children . The concomitant use of alcohol or other central nervous system depressants may have an additive effect. Patient should be warned accordingly.

Usage in Pregnancy : An increase risk of congenital malformations associated with the use of minor tranquilizers (chlordiazepoxide, diazepam and merprobamate) during the first trimester of pregnancy has been suggested in several studies. Because use of these drugs is rarely a matter of urgency . Their use during this period should be almost always avoided.

Chlordiazepoxide may pass into breast milk and could harm a nursing baby . Do not use this medication without telling your doctor if you are breast- feeding a baby.
The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. Patients should be advised that if they become pregnant they should communicate with their physicians about the desirability of discontinuing the drug.
Withdrawal symptoms of the barbiturate type have occurred after the discontinuing of benzodiazepines.
In elderly and debilitated patients , it is recommended that the dosage be limited to the smallest effective amount to preclude the d evelopment of ataxia or oversedation (10 mg or less per day initially , to be increased gradually as needed and tolerate).
In general , the concomitant administration of **Psicodex 5®** and other psychotropic agents is not recommended . The usual precautions in treating patients with impaired renal or hepatic function should be observed. Accidental falls are common in elderly patients who take benzodiazepines . Use caution to avoid falling or accidental injury while you are taking chlordiazepoxide.
Do not drink alcohol while taking chlordiazepoxide . This medication can increase the effects of alcohol.

Side Effects.

The necessity of discontinuing therapy because or undesirable effects has been rare . Drowsiness, ataxia and confusion have been reported in some patients - particularly the elderly and debilitated. While these effects can be avoided in almost all instances by proper dosage adjustment, they have occasionally been observed at the lower dosage ranges . In a few instances , syncope has been r eported. Other adverse reaction reported during therapy include isolated instances of skin eruptions, edema , minor menstrual irregularities, nausea and constipation , extrapyramidal symptoms, as well as increased & decreased libido. Such side effects have been infrequent & are generally controlled with reduction of dosage.
Blood dyscrasias (including agranulocytosis) , Jaundice and hepatic dysfunction have occasionally been reported during therapy . When **Psicodex 5®** treatment is protracted , periodic blood counts and liver function tests are advisable.

Overdosage

Manifestations of **Psicodex 5®** overdosage include somnolence , confusion , coma , and diminished reflexes. Respiration , pulse and blood pressure should be monitored , as in all cases of drug overdosage, although, in general , these effects have been minimal following **Psicodex 5®** overdosage.
General Supportive measures should be employed, along with immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Dialysis is of limited value.

Storage

- Store in a cool and dry place, below 25°C.
- Keep out of the reach of children.
- Store away from heat and direct light and away form excess heat and moisture (not in the bathroom)
- Throw away any medication that is outdated or no longer needed.

THIS IS A MEDICINE

- Medicines are products which affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINES OUT OF THE REACH OF CHILDREN

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PHARMADEX S.A.L.
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