MODEX

Tablets

Composition

Each tablet contains:

Clinidium bromide	2.5 mg
Chlordiazepoxide	5 mg

Action

Modex combines the anticholinergic action of Clinidium bromide with the anxiolytic effect of Chlordiazepoxide.
Chlordiazepoxide is effective in the relief of anxiety and tension. It is indicated when anxiety, tension or apprehension are significant components of the clinical profile.

Clinidium bromide is a synthetic anticholinergic agent. In experimental and clinical studies, it has been shown to have a pronounced antispasmodic and antisecretory effect on the gastrointestinal tract.

Indications

Control of hypersecretion, hypermotility and emotional factors associated with gastrointestinal disorders due to anxiety and tension states.

Contraindications

- Known hypersensitivity to either of the components of the preparation.
- Presence of glaucoma, and in patients with prostatic hypertrophy and benign bladder neck obstruction.
- During the first trimester of pregnancy and in breastfeeding.

Warnings

Because of the benzodiazepine component, prolonged use may cause dependence.

Withdrawal symptoms similar in character to those noted with barbiturates and alcohol have occurred following abrupt discontinuation of benzodiazepine drugs. These symptoms include convulsions, tremor, abdominal and muscle cramps, vomiting and sweating.

When discontinuing therapy in patients who have been treated with this preparation for prolonged periods, the dosage should be decreased gradually to avoid the possibility of withdrawal symptoms.

Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, rage, insomnia, sleep disturbances and stimulation have been reported. Should these occur, use of the drug should be discontinued.

Pregnancy

Category D

Benzodiazepines have the potential to cause fetal harm when administered to pregnant women. If this drug is used during pregnancy or the patient becomes pregnant while taking this drug, she should be informed of the potential hazard to the fetus.

Benzodiazepines assumed capable of causing an increased risk of congenital abnormalities when administered to pregnant women during the first trimester. For this reason, Modex administration should be avoided during the first trimester of pregnancy.

Administration of Modex in the last two trimesters of pregnancy and in women of childbearing potential requires that the expected benefits weighed against the possible hazards to the mother and fetus.

The possibility that women of childbearing potential may be pregnant when therapy is instituted should be considered. Patients should be advised that if they become pregnant during therapy or intend to become pregnant, they should refer to their physician about the desirability of discontinuing the drug.

Nursing Mothers
Chlordiazepoxide or its metabolites may be excreted in breast milk, and use by nursing mothers may cause sedation in the infant.
Clinidium may tend to inhibit lactation.
Modex should not be administered to nursing mothers.

Adverse Reactions
Adverse effects relevant to Clinidium are those typical of anticholinergic agents, e.g. dryness of the mouth, constipation and urinary hesitancy, especially at the beginning of the treatment.

In common with other benzodiazepines, the following side effects have been occasionally reported: drowsiness, fatigue, ataxia, hypotension, gastrointestinal disturbances, visual disturbances, skin rash, urinary retention, headache, confusion, vertigo, change in libido, blood dyscrasias, jaundice, minor menstrual irregularities, extrapyramidal symptoms, changes in EEG patterns (low voltage fast activity) and paradoxical reactions such as acute hyper-excitation states .

In a few instances, syncope has been reported.
Drowsiness and fatigue, if they occur, are usually observed at the beginning of therapy. Usually, they diminish during continued treatment, or when the dosage is decreased.

Precautions
In elderly or debilitated patients, the initial dose should be low. Dosage increments should be made gradually, according to the response of the patient, in order to preclude drowsiness, ataxia, excessive sedation or confusion.

Although hypotension has rarely occurred, this drug should be administered with caution to patients in whom a drop of blood pressure might lead to cardiac complications.

Caution should be exercised in patients with impaired renal or hepatic function. When Modex treatment is protracted, periodic blood counts and liver function tests are recommended.

Patients who experience drowsiness during treatment should be warned that their ability to perform potentially hazardous tasks requiring mental alertness or physical coordination, such as driving a vehicle or operating machinery, might be impaired.

Drug Interactions
Modex / Alcohol/ General Anaesthetics/ CNS Depressants/ Monoamine Oxidase Inhibitors/ Phenothiazines/ Tricyclic Antidepressants
Concurrent use may intensify sedative and atropine like effects.

Dosage and Administration
Because of the varied individual responses to tranquilizers and anticholinergics, the optimum dosage of Modex varies according to the diagnosis and response of each individual patient.

Therefore, the dosage should be individualized for maximum beneficial effects. The usual maintenance dosage is 1 or 2 tablets, 3 or 4 times a day, administered before meals and at bedtime. In elderly and debilitated patients, it is recommended that the initial dosage should not exceed 2 Modex tablets per day, to be increased gradually as needed and tolerated.

Over Dosage
Manifestations

Manifestations of chlordiazepoxide over dosage include somnolence, confusion, coma and diminished reflexes. Respiration, pulse and blood pressure should be monitored, as in all cases of drug over dosage, although, in general, these effects have been minimal following chlordiazepoxide over dosage.
While either of its components may produce the signs and symptoms of Modex over dosage, usually the symptoms due to the anticholinergic effects of Clinidium bromide will be most prominent. The symptoms of Clinidium over dosage are excessive dryness of mouth, blurring of vision, urinary hesitancy and constipation.

Treatment
General supportive measures should be employed, along with immediate gastric lavage.

0.5-2 mg of Physostigmine should be administered I.V. at a rate of no more than 1 mg/min. This may be repeated in 1-4 mg doses if arrhythmias, convulsions or deep coma recur. Intravenous fluids should be administered, and an adequate airway maintained.

Hypotension may be combated by the use of noradrenaline or metaraminol.
Methylphenidate or caffeine and sodium benzoate may be administered to combat CNS-depressive effects. Dialysis is of limited value. If excitation occurs, barbiturates should not be used.

Presentation
Box of 20 tablets.