dose that is well tolerated. The medication should preferably be taken with liquid, half an hour before food. Tablets can either be swallowed whole or crushed.

CONTRAINDICATIONS
Poxidium is contraindicated for patients with known hypersensitivity to chlordiazepoxide or clidinium bromide, and also in the presence of glaucoma, prostatic hypertrophy, myasthenia gravis, severe respiratory failure, sleep apnoea syndrome and severe liver failure.

WARNINGS PRECAUTIONS
Depending on dosage, administration and individual susceptibility, poxidium may modify the patient’s reactions (e.g. driving ability, behaviour in traffic). Blood, renal and hepatic function tests are recommended if treatment is given for prolonged periods.

Dependency:
The use of benzodiazepines may lead to dependence. The risk of dependence increases with dose and duration of treatment and in pre-disposed patients. Withdrawal symptoms mainly appear following abrupt termination of treatment and are limited in milder cases to tremor restlessness, anxiety, headaches and poor concentration. Symptoms such as sweating, muscle and abdominal cramps, impaired perception and, more rarely, delirium and cerebral convulsive seizures may also occur. Depending on the duration of action of the substance concerned, withdrawal phenomena commence a few hours to a week or more after discontinuation of treatment.

In order to minimize the risk of dependence, benzodiazepines should be prescribed only after careful consideration of the indication and taken for as short a period as possible (generally no longer than four weeks when used as a hypnotic, for example). The need for continuation of treatment should be reviewed regularly, the risk-benefit relationship of more prolonged treatment is less clear hence it is
indicated only in certain patients (e.g. those with panic attacks). In order to avoid withdrawal phenomena, the drug should be discontinued by tapering off the dose in all patients. Should withdrawal phenomena occur close medical monitoring and support of the patient are required.

**Pregnancy and Lactation**

There is clear evidence of a risk to the human foetus. In view of the symptomatic indications of Poxidium, this medication must not be administered during pregnancy or lactation.

**SIDE EFFECTS**

Side effects such as dry mouth, constipation, micturition disorders, visual disorders and tachycardia may occasionally occur. In elderly patients, chlordiazepoxide may sometimes trigger slight drowsiness, especially at the beginning of treatment. This usually disappears spontaneously or in response to a dosage reduction, transient anterograde amnesia may occur.

Paradoxical reactions such as restlessness, excitation, agitation, aggression, hallucinations, behavioural disorders are associated with administration of benzodiazepines. These side effects are more common in elderly patients.

In such cases, treatment must be withdrawn and adequate patient monitoring and support instituted.

Dizziness, ataxia and muscle weakness may occur especially at the start of treatment. These symptoms generally regress once the dosage has been reduced or as treatment continues.

Allergic reactions (e.g. exanthema) may very occasionally occur.

**Drug Interactions**

Caution should be exercised if Poxidium is taken with medicines that attenuate the central nervous system (e.g. tranquillisers, hypnotics, antiepileptics and opiates) as the effects of these drugs can be mutually potentiated.

The metabolism of chlordiazepoxide can be inhibited by ketoconazole, cimetidine or disulfiram.

If Poxidium is taken concurrently with preparations containing anticholinergic ingredients, e.g. amantadine, various antihistamines, butyrophenones, phenothiazines, tricyclic and tetracyclic antidepressants, anti-Parkinsonian agents, anti-arrhythmics (such as quinidine and disopyramide), pirenzepine, anticholinergic spasmolytics or asthma medication, the anticholinergic action of clidinium is potentiated. Muscle relaxants may potentiate the effect of chlordiazepoxide. The absorption of other medications can be slowed down by the effect on the gastrointestinal tract.

Chlorediazepoxide is hydroxylated by the isoenzyme CYP450 3A4. Although no specific interaction studies are available, caution is basically exercised during concomitant administration of medicines that inhibit or that are metabolised by this isoenzyme (e.g. macrolide antibiotics, azol type antifungal agents, calcium antagonists, protease inhibitors, ergot alkaloids and antidepressants). During treatment with Poxidium, patients should avoid alcohol since the individual response cannot be foreseen.

**OVERDOSAGE**

Measures recommended for accidental or deliberate overdose are evacuation of the stomach [emptying of stomach contents by means of a gastric tube, eg. in the case of acute poisoning (usually followed by gastric lavage)], maintenance of airway patency and patient monitoring. If symptoms attributable to chlordiazepoxide pre-dominate, Anexate® (active ingredient: flumazenil) is indicated.

**STORAGE**

Store between 15-25°C.

**PRESENTATIONS**

**Tablets**

POXIDIUM: Chlordiazepoxide 5 mg and Clidinium bromide 2.5 mg/tablet

Excipients: Lactose, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Silicon Dioxide, Magnesium Stearate and Instacoat Aqua II IA-II-30106 green.