

# Clob<sup>®</sup>

Clobazam

## Description

Clobazam (Clob<sup>®</sup>) was the first anxiolytic agent belonging to the class of 1,5-benzodiazepines. It is suitable for the short-term relief of anxiety that is severe, disabling or subjecting the individual to unacceptable distress, occurring alone or in association with insomnia.

## Mode of action

Clobazam (Clob<sup>®</sup>) attaches to the specific site on the GABA receptor/chloride channel complex and potentiates the effect of GABA, an important inhibitory transmitter in the CNS which acts by opening chloride ion channels into cells.

## Pharmacokinetics

Clobazam (Clob<sup>®</sup>) is rapidly and completely absorbed after oral administration. Co-administration of clobazam with food slows the rate of drug absorption but does not influence the completeness of absorption. As it is highly lipophilic, clobazam is readily distributed to most tissues. The mean elimination half life of clobazam is 20 hrs (10 to 50 hrs) and protein binding is 90%. Clobazam (Clob<sup>®</sup>) is almost entirely eliminated from the body by biotransformation in the liver. Up to 97% of the dose is excreted in the urine, with only about 2% as unchanged drug.

## Composition

Clob<sup>®</sup> Tablet: Each tablet contains Clobazam BP 10 mg.

## Indications

Clobazam (Clob<sup>®</sup>) is indicated for the treatment of short-term relief (2-4 weeks) only of anxiety that is severe disabling or subjecting the individual to unacceptable distress, occurring alone or in association with insomnia or short-term psychosomatic, organic or psychotic illness. It may be used as adjuvant therapy in epilepsy. The use of it in schizophrenia or other psychotic illness is recommended only as adjuvant.

## Dosage & administration

Anxiety: 20-30 mg daily in divided doses or as a single dose at bed time, increased in severe anxiety to a maximum of 60 mg daily in divided doses. Elderly: 10-20 mg daily. Sleep disturbances: 10-20 mg as a single dose at bed time. Epilepsy: Adults: 20-30 mg daily, maximum 60 mg daily; Child over 3 years: Not more than half of the adult dose.

## Contraindications

Respiratory depression, acute pulmonary insufficiency, severe hepatic impairment, sleep apnoea syndrome, myasthenia gravis, any history of drug or alcohol dependence.

## Side effects

Clobazam is generally well tolerated and adverse reactions are few mild and transient. Adverse effect such as drowsiness, dizziness, headache, nausea or dryness of mouth has been reported.

## Use in pregnancy & lactation

The safety of clobazam in pregnancy and lactation is not yet established. It should not be used in pregnancy and lactation unless there are compelling reasons for doing so.

## Precautions

Clobazam should be used with caution in renal or hepatic impairment. Special care should be taken in case of muscle weakness and respiratory disease.

## Drug interactions

Alcohol increases serum concentration of clobazam. Hypnotics or antidepressants with sedative activity may cause an increase in side effects, particularly tiredness or drowsiness. Phenobarbital increases clobazam plasma concentrations. Enzyme inhibitor drugs (cimetidine, propoxyphene, omeprazole) may interfere with the metabolism of oxidatively biotransformed benzodiazepines but no information is available about clobazam kinetics in patients concomitantly receiving such drugs.

## Overdosage

In mild cases, symptoms include drowsiness, mental confusion and lethargy, in more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death.

Following overdose with clobazam, vomiting should be induced within one hour if 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.

Consideration should be given to the use flumazenil as benzodiazepine antagonist.

## Storage

Store in a cool and dry place, protected from light.

## Packaging

Clob<sup>®</sup> Tablet: Each carton contains 10X10 tablets in blister pack.

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