Clonazepam Neuraxpharm 0.5 mg, 1 mg and 2 mg tablets

Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Tablets containing 0.5 mg, 1 mg or 2 mg clonazepam. Indication: All clinical forms of epileptic disease and seizures in infants, children and adults, especially absence seizures (petit mal), including atypical absence; primary or secondarily generalised tonic-clonic (grand mal), tonic or clonic seizures; partial (focal) seizures with elementary or complex symptomatology; various forms of myoclonic seizures, myoclonus and associated abnormal movements. Dosage and administration: Adults: Initial dosage should not exceed 0.5 mg/day, normal maintenance dosage is 4 to 8 mg. Elderly: Recommended that the initial dose should not exceed 0.5 mg/day. These are total daily dosages which should be divided into 3 or 4 doses taken at intervals during the day. Larger doses may be given at the discretion of the physician, up to a maximum of 20 mg daily. The maintenance dose should be attained after 2 to 4 weeks treatment. Paediatric population: To ensure optimum dosage adjustment 0.5 mg tablets should be used. Initial dosage should not exceed 0.25 mg/day for infants and small children (1 to 5 years) and 0.5 mg/day for older children. Maintenance doses normally fall within the ranges: Infants (0 to 1 year) 0.5 to 1 mg/day, small children (1 to 5 years) 1 to 3 mg/day, children (5 to 12 years) 3 to 6 mg/day. Hepatic impairment: Not to be used by patients with severe hepatic impairment. Adjust dose to individual requirements in patients with mild to moderate hepatic impairment. Tablets for oral administration. Treatment should be started with low doses and the dose may be increased progressively until the most suitable maintenance dose has been determined according to clinical response and tolerance. The daily dose should be divided into 3 or 4 equal doses. If the dose is not equitably divided, the largest dose should be given before bedtime. Once the maintenance dose has been reached, a single dose may be given in the evening. Simultaneous administration of more than one antiepileptic drug is a common practice in the treatment of epilepsy and may be undertaken with clonazepam. Contraindications: Known hypersensitivity to benzodiazepines, hypersensitivity to the active substance or to any of the excipients, acute pulmonary insufficiency, severe respiratory insufficiency, sleep apnoea syndrome, myasthenia gravis, severe hepatic insufficiency. Clonazepam must not be used in patients in coma, or in patients known to be abusing pharmaceuticals, drugs or alcohol. Special warnings and precautions: Clonazepam should be used with caution in patients with cataracts or pulmonary insufficiency, or with impairment of renal or hepatic function, and in the elderly or debilitated. In these cases dosage should generally be reduced. The dosage of clonazepam must be carefully adjusted to individual requirements in patients with pre-existing disease of the respiratory system (e.g. COPD) or the liver and in patients undergoing treatment with other centrally acting medications or anticonvulsant agents. Use clonazepam with particular caution in patients with spinal or cerebellar ataxia, in the event of acute intoxication with alcohol or drugs and in patients with severe liver damage. Do not interrupt treatment abruptly. As with other antiepileptic drugs, treatment with clonazepam even of short duration, must be gradually withdrawn by dose reduction in view of the risk of precipitating status epilepticus. This precaution must also be taken when withdrawing another drug while the patient is still receiving clonazepam therapy. Prolonged use of benzodiazepines may result in dependence with withdrawal symptoms on cessation of use. Suicidal behaviour: Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviour and any treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Patients with a history of depression and/or suicide attempts should be kept under close supervision. Concomitant use with alcohol / CNS depressants: The concomitant use of clonazepam with alcohol or CNS depressants should be avoided. Such use has the potential to increase the clinical effects of clonazepam possibly including severe sedation. In patients with severe liver disease or cardiorespiratory depression. Clonazepam should be used with extreme caution in patients with a history of alcohol or drug abuse. Risk from concomitant use of opioids: Concomitant use of clonazepam and opioids may result in sedation, respiratory depression, coma and death. Concomitant prescribing of sedatives such as benzodiazepines or related drugs with opioids should be reserved for patients for whom alternative treatment options are not possible. If clonazepam is prescribed concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible. Patients should be followed closely for signs and symptoms of respiratory depression and sedation. It is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms. Driving: Use of drugs of this type, clonazepam may modify the patient’s reactions. Dependency: Use of benzodiazepines may lead to dependence. Concomitant prescribing of benzodiazepines may lead to the development of physical and psychological dependence on these products. Long-term or high-dose treatment may lead to reversible disorders such as dizziness, reduced coordination of movements and gait disorder (ataxia), nystagmus and double vision (diplopia). The risk of antegrade amnesia, which may occur at therapeutic dosages, increases at higher dosages. Amnestic effects may be associated with inappropriate behaviour. With certain forms of epilepsy, an increase in the frequency of seizures during long-term treatment is possible. The risk of dependence increases with dose and duration of treatment: it is also greater in patients with a medical history of alcohol and/or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. Abrupt withdrawal of the drug should therefore be avoided and treatment – even if only of short duration – should be terminated by gradually reducing the daily dose. The risk of withdrawal symptoms is increased when benzodiazepines are given by day-time sedatives. Cessation tolerance: Clonazepam tablets contain lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Phenytoin Clonazepam should be used with care in patients with phenytoin. Paediatric population: In infants and small children clonazepam may cause increased production of saliva and bronchial secretion. Therefore special attention must be paid to maintaining patency of the airways. For further information please refer to SmPC. Pregnancy and lactation: Clonazepam should only be administered to pregnant women if the potential benefits outweigh the risk to the foetus. Mothers undergoing treatment with clonazepam should not breastfeed. Undesirable effects: Common / occasional (≥1/100): Nystagmus. The following undesirable effects occur relatively frequently are usually transient and generally disappear spontaneously: somnolence, slowed reaction, muscular hypotonia, dizziness, ataxia, muscle weakness and fatigue. Psychiatric disorders include impaired consciousness, confusion, state delirium, depression, excitability, irritability, agitation, nervousness, hostility, anxiety, sleep disturbances, nightmares, vivid dreams, psychotic disorders and activation of new types of seizures may be precipitated. Dependence may occur. CNS disorders include somnolence, slowed reaction, muscular hypotonia, dizziness and ataxia. Particularly in long-term or high-dose treatment, reversible disorders such as a slowing or slurring of speech (dysarthria), reduced coordination of movements and gait disorder (ataxia) and nystagmus may occur. Anterograde amnesia may occur using benzodiazepines at therapeutic dosages, the risk increasing at higher dosages. Amnestic effects may be associated with inappropriate behaviour. Other adverse effects include diplopia, cardiac failure (including cardiac arrhythmia), salivary or bronchial hypersecretion with drooling in infants and small children. Refer to SmPC for full details. Legal category: POM. Presentation & cost: 100 x 0.5 mg tablets £32.27; 100 x 1 mg tablets £41.95; 100 x 2 mg tablets £34.99. Marketing authorisation holder and numbers: Neuraxpharm UK Limited, Unit 12, Farnborough Business Centre, Eelmoor Road, Farnborough GU14 7XA, UK. (0.5 mg) PL 4978/0060, (1 mg) PL 4978/0061, (2 mg) PL 4978/0052. Date of revision of test: August 2022.

References:
1. BNF. Available at: https://bnf.nice.org.uk/drugs/clonazepam/medicinal-forms/ [Accessed Oct 2022].
3. NXUK/0922/05 Date of preparation October 2022.

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