BIZLO

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for (Baclofen Tablets 10 mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Baclofen depresses monosynaptic and polysynaptic reflex transmission, probably by stimulating the GABA -receptors, this stimulation in turn inhibiting the release of the excitatory amino acids glutamate and aspartate. Neuromuscular transmission is unaffected by Baclofen.

INDICATIONS: Baclofen is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, and traumatic partial section of the cord.

DOSAGE AND ADMINISTRATION: As directed by the Physician. Baclofen 10 mg uncoated tablets should be administered orally.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. and peptic ulceration.

WARNINGS & PRECAUTIONS: Psychiatric and nervous system disorders Psychotic disorders, schizophrenia, depressive or manic disorders, confusional states or Parkinson's disease may be exacerbated by treatment with BIZLO. Patients suffering from these conditions should therefore be treated cautiously and kept under close surveillance. Suicide and suicide-related events have been reported in patients treated with baclofen. In most cases, the patients had additional risk factors associated with an increased risk of suicide including alcohol use disorder, depression and/or a history of previous suicide attempts. Close supervision of patients with additional risk factors for suicide should accompany drug therapy. Patients (and caregivers of patients) should be alerted about the need to monitor for clinical worsening, suicidal behaviour or thoughts or unusual changes in behaviour and to seek medical advice immediately if these symptoms present. Cases of misuse, abuse and dependence have been reported with baclofen. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of baclofen misuse, abuse or dependence e.g. dose escalation, drug-seeking behaviour, development of tolerance. ***Epilepsy:*** BIZLO may also exacerbate epileptic manifestations but can be employed provided appropriate supervision and adequate anticonvulsive therapy are maintained. ***Others:*** BIZLO should be used with extreme care in patients already receiving antihypertensive therapy, BIZLO should be used with caution in patients suffering from cerebrovascular accidents or from respiratory or hepatic impairment. Since unwanted effects are more likely to occur, a cautious dosage schedule should be adopted in elderly and patients with spasticity of cerebral origin. ***Renal impairment:*** Baclofen should be used with caution in patients with renal impairment and should be administered to end stage renal failure patients only if the expected benefit outweighs the potential risk. Neurological signs and symptoms of overdose including clinical manifestations of toxic encephalopathy (e.g. confusion, disorientation, somnolence and depressed level of consciousness) have been observed in patients with renal impairment taking oral baclofen at doses of more than 5mg per day. Patients with impaired renal function should be closely monitored for prompt diagnosis of early symptoms of toxicity. Particular caution is required when combining BIZLO to drugs or medicinal products that can significantly affect renal function. Renal function should be closely monitored and BIZLO daily dosage adjusted accordingly to prevent baclofen toxicity. Cases of baclofen toxicity have been reported in patients with acute renal failure. Besides discontinuing treatment, unscheduled haemodialysis might be considered as a treatment alternative in patients with severe baclofen toxicity. Haemodialysis effectively removes baclofen from the body, alleviates clinical symptoms of overdose and shortens the recovery time in these patients. ***Urinary disorders*** under treatment with BIZLO neurogenic disturbances affecting emptying of the

bladder may show an improvement. In patients with pre-existing sphincter hypertonia, acute retention of urine may occur; the drug should be used with caution in such cases. ***Laboratory tests:*** In rare instances elevated aspartate aminotransferase, blood alkaline phosphatase and blood glucose levels in serum have been recorded. Appropriate laboratory tests should be performed in patients with liver diseases or diabetes mellitus in order to ensure that no drug induced changes in these underlying diseases have occurred. ***Excipients:*** BIZLO tablets contain wheat starch. Wheat starch may contain gluten, but only in trace amounts. Taking BIZLO tablets is therefore considered safe for people with coeliac disease. ***Abrupt withdrawal:*** Treatment should always, (unless serious adverse effects occur), be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks. Anxiety and confusional state, delirium, hallucination, psychotic disorder, mania or paranoia, convulsion (status epilepticus), dyskinesia, tachycardia, hyperthermia, rhabdomyolysis and temporary aggravation of spasticity have been reported with abrupt withdrawal of BIZLO, especially after long term medication. Drug withdrawal reactions including postnatal convulsions in neonates have been reported after intrauterine exposure to oral BIZLO. Treatment should always, (unless serious adverse effects occur), therefore be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks. ***Paediatric patients*** there are very limited clinical data on the use of BIZLO in children under the age of one year. Use in this patient population should be based on the physician's consideration of individual benefit and risk of therapy. ***Posture and balance*** BIZLO should be used with caution when spasticity is needed to sustain upright posture and balance in locomotion.

DRUG INTERACTIONS: ***Levodopa/dopa decarboxylase (DDC) inhibitor (Carbidopa)***

In patients with Parkinson's disease receiving treatment with BIZLO and levodopa (alone or in combination with DDC inhibitor, carbidopa), there have been reports of mental confusion, hallucinations, nausea and agitation. Worsening of the symptoms of Parkinsonism has also been reported. Hence, caution should be exercised during concomitant administration of BIZLO and levodopa/carbidopa. ***Drugs causing Central Nervous System (CNS) depression*** Increased sedation may occur when BIZLO is taken concomitantly with other drugs causing CNS depression including other muscle relaxants (such as tizanidine), with synthetic opiates or with alcohol. The risk of respiratory depression is also increased. In addition, hypotension has been reported with concomitant use of morphine and intrathecal baclofen. Careful monitoring of respiratory and cardiovascular functions is essential especially in patients with cardiopulmonary disease and respiratory muscle weakness. ***Antidepressants*** During concomitant treatment with tricyclic antidepressants, the effect of BIZLO may be potentiated, resulting in pronounced muscular hypotonia. ***Lithium*** Concomitant use of oral BIZLO and lithium resulted in aggravated hyperkinetic symptoms. Thus, caution should be exercised when BIZLO is used concomitantly with lithium.

ADVERSE REACTIONS: Sedation, somnolence, Respiratory depression, confusional state, dizziness, hallucination, depression, fatigue, insomnia, euphoric mood, muscular weakness, ataxia, tremor, nightmare, myalgia, headache, nystagmus, dry mouth, Paraesthesia, dysarthria, dysgeusia, Visual impairment, accommodation disorder, Cardiac output decreased, Rash, hyperhidrosis, Pollakiuria, enuresis, dysuria, Hypotension, Cardiac output decreased

MARKETED BY:

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(Additional information is available on request)