

BIZLO OD 30

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

Abbreviated Prescribing information for BIZLO OD 30 (Baclofen Sustained Release Tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: BIZLO OD depresses monosynaptic and polysynaptic reflex transmission, probably by stimulating the GABA_B-receptors, this stimulation in turn inhibiting the release of the excitatory amino acids glutamate and aspartate. Neuromuscular transmission is unaffected by BIZLO OD.

INDICATIONS: For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury.

DOSAGE AND ADMINISTRATION: As directed by the Physician. BIZLO OD should be taken during meals with a little liquid.

CONTRAINDICATION: Hypersensitivity to baclofen or to any of the excipients, Peptic ulceration.

WARNINGS & PRECAUTIONS: *Psychiatric and nervous system disorders* may be exacerbated by treatment with baclofen as suicide and suicide-related events, cases of misuse, abuse and dependence have been reported with baclofen. *Epilepsy* may also exacerbate but can be employed provided appropriate supervision and adequate anticonvulsive therapy are maintained. *Others:* It should be used with extreme care in patients already receiving antihypertensive therapy, in patients suffering from cerebrovascular accidents or from respiratory or hepatic impairment, in elderly and patients with spasticity of cerebral origin unwanted effects are more likely to occurs. *Renal impairment:* it should be administered to end stage renal failure patients only. Neurological signs and symptoms of overdose including clinical manifestations of toxic encephalopathy have been observed in patients with renal impairment taking oral baclofen at doses of more than 5mg per day. *Urinary disorders:* 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:* 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. *Abrupt withdrawal:* Treatment should always be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks. *Children and adolescents:* BIZLO OD is not suitable for use in children under 33 kg body weight. *Posture and balance:* It should be used with caution when spasticity is needed to sustain upright posture and balance in locomotion.

DRUG INTERACTIONS: BIZLO OD 30, a medication containing baclofen, interacts with several drugs: 1. With levodopa/carbidopa, it may cause confusion, hallucinations, nausea, and worsen Parkinson's symptoms. 2. Combined with CNS depressants like muscle relaxants or opioids, it can increase sedation and respiratory depression. 3. Tricyclic antidepressants can potentiate baclofen's effects, causing muscular hypotonia. 4. Lithium and baclofen together may worsen hyperkinetic symptoms. 5. Concurrent use with antihypertensives may lead to excessive blood pressure drops. 6. Drugs affecting renal function can prolong baclofen's effects by reducing its excretion, potentially causing toxicity.

ADVERSE REACTIONS: *Very common:* Sedation, Somnolence, Nausea, *Common:* Respiratory depression, confusional state, dizziness, hallucination, depression, fatigue, insomnia, euphoric mood, muscular weakness, ataxia, tremor, nightmare, myalgia, headache, nystagmus, dry mouth, Visual impairment, accommodation disorder, Cardiac output decreased, Hypotension, Gastrointestinal disorder, Constipation, diarrhoea, retching, vomiting, Rash, hyperhidrosis, Pollakiuria, dysuria, *Rare:* Paraesthesia, dysarthria, dysgeusia, Abdominal pain, Hepatic function abnormal, Urinary retention, Erectile dysfunction, *Very Rare:* Hypothermia, *Unknown:* Sleep apnoea syndrome, Bradycardia, Urticaria, Drug withdrawal syndrome, Blood glucose increased.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/BIZLO OD 30 mg/Dec 19/01/ABPI

(Additional information is available on request)