NOVARTIS

LIORESAL® (baclofen)

10 mg Tablets

Basic Succinct Statement
Version 3.2

CODE: BSS RD 09 DEC 19; APPR 29 MAY 20

This material is only meant for Healthcare Professionals

LIORESAL®

Important note: Before prescribing, consult the full prescribing information.

Presentation: Baclofen tablets, scored, of 10mg.

Indications: Spasticity of the skeletal muscles in multiple sclerosis. Spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic, or unknown origin: e.g. spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitits, traumatic paraplegia or paraparesis, and compression of the spinal cord; muscle spasticity of cerebral origin, especially where due to infantile cerebral palsy. In spasticity due to cerebrovascular accident or degenerative or neoplastic brain disease, Lioresal is less suitable owing to the likelihood of intolerance, but it may be tried if administered cautiously.

Dosage: ♦**Adults** Starting dose: 15 mg/day. Maintenance dose range: 30 to 80 mg/day in divided doses. ♦**Children**: Lioresal tablets are not suitable for use in children with a body weight below 33 kg. Starting dose: 0.3 mg/kg/day. Maintenance dose range: 0.75 to 2 mg/kg/day in divided doses. Maximum daily dose is 40 mg/day in children below 8 years of age and 60 mg/day in children above 8 years of age. ♦**Patients on haemodialysis**: 5 mg/day.

Contraindications: Known hypersensitivity to baclofen or to any of the excipients.

Warnings/Precautions: ♦Caution is recommended in patients with epilepsy, psychiatric disorders, confusional states, Parkinson's disease, peptic ulcers, cerebrovascular or liver disease, hepatic, renal or respiratory insufficiency, sphincter hypertonia or diabetes mellitus. Avoid abrupt discontinuation. ♦Close supervision is recommended in patients with additional risk factors for suicide. ♦**Pregnancy**: Should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus. Drug withdrawal reactions including postnatal convulsions may occur in newborns after intrauterine exposure to oral Lioresal. Lioresal may be administered to newborn with gradual reduction in dose to control and prevent the drug withdrawal reactions. ♦**Breast-feeding**: No undesirable effects are to be expected for the infant. ♦**Driving and using machines**: Refrain from driving or operating machines if experiencing somnolence, dizziness, visual disturbance or similar effects. ♦Caution is recommended when spasticity is needed to sustain an upright posture and balance in locomotion.

Adverse reactions: ♦**Very common (≥10%):** sedation, somnolence, nausea. ♦**Common (≥1 to <10%):** convulsions, respiratory depression, fatigue, confusional state, dizziness, headache, insomnia, euphoric mood, depression, muscular weakness, ataxia, tremor, hallucination, nightmare, myalgia, nystagmus, dry mouth, accommodation disorder and visual impairment, decreased cardiac output, hypotension, gastrointestinal disorder, retching, vomiting, constipation, diarrhoea, hyperhydrosis, rash, pollakiuria, enuresis, dysuria. ♦**Rare (≥0.01 to <0.1%):** paraesthesia, dysarthria, dysgeusia, abdominal pain, hepatic function abnormal, urinary retention, erectile dysfunction. ♦**Very rare (<0.01%):** hypothermia. ♦**Frequency not known:** urticaria, bradycardia, drug withdrawal syndrome (including postnatal convulsions reported after intra-uterine exposure to oral Lioresal), increased blood glucose.