

Abbreviated Prescribing Information

Baclofen Mercury Pharmaceuticals 5mg, 20mg tablets

Consult the Summary of Product Characteristics (SmPC) before prescribing.

Additional information is available on request.

Presentations: Each tablet contains 5mg or 20mg baclofen. **Indication:** 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, traumatic partial section of the cord. Relief of spasticity of voluntary muscle arising from e.g., cerebrovascular accidents, cerebral palsy, meningitis, traumatic head injury. *Paediatric population: 0 to <18 years:* Symptomatic treatment of spasticity of cerebral origin, especially where due to infantile cerebral palsy, as well as following cerebrovascular accidents or in the presence of neoplastic or degenerative brain disease. Symptomatic treatment of muscle spasms occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic, or unknown origin such as multiple sclerosis, spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paraplegia or paraparesis, and compression of the spinal cord. Patient selection is important when initiating baclofen therapy; it is likely to be of most benefit in patients whose spasticity constitutes a handicap to activities and/or physiotherapy. Treatment should not be commenced until the spastic state has become stabilised. **Dose:** Baclofen is given orally in either tablet or liquid form. The lowest dose compatible with an optimal response is recommended. Careful titration of dosage is essential (particularly in the elderly) until the patient is stabilised. Once the maximum recommended dose has been reached, if the therapeutic effect is not apparent within 6 weeks a decision whether to continue with baclofen should be taken. Discontinuation of the treatment should always be gradual by successively reducing the dosage over a period of approximately 1 to 2 weeks, except in overdose-related emergencies, or where serious adverse effects have occurred. **Adults:** 15 mg daily, preferably in divided doses. Satisfactory control of symptoms is usually obtained with doses of up to 60 mg daily, but a careful adjustment is often necessary to meet the requirements of each individual patient. The dose may be increased slowly if required, but a maximum daily dose of more than 100 mg is not advised unless the patient is in hospital under careful medical supervision. Small frequent dosage may prove better in some cases than larger spaced doses. Some patients benefit from the use of baclofen only at night to counteract painful flexor spasm. A single dose given approximately 1 hour prior to performance of specific tasks such as washing, dressing, shaving, physiotherapy, will often improve mobility. **Special populations: Elderly patients (≥ 65 years):** Small doses should be used at the start of treatment, the dose being titrated gradually against the response, under careful supervision. There is no evidence that the eventual average maximum dose differs from that in younger patients. *Renal impairment:* Low dosage of baclofen should be selected i.e., approx. 5 mg daily. To be administered to end stage renal failure patients only if the expected benefit outweighs the potential risk. These patients should be closely monitored for prompt diagnosis of early signs and/or symptoms of toxicity (e.g., somnolence, lethargy). *Hepatic impairment:* Should be prescribed with caution. Baclofen has the potential of elevating liver enzymes. *Patients with spastic states of cerebral origin:* Cautious dosage schedule be adopted and patients be kept under appropriate surveillance. *Paediatrics:* To be started with a very low dose (corresponding to approximately 0.3 mg/kg a day), in 2-4 divided doses, preferably in 4 divided doses. The dosage should be cautiously raised at about 1-week intervals, until it becomes sufficient for the child's individual requirements. The usual daily dosage for maintenance therapy ranges between 0.75 and 2 mg/kg body weight. The total daily dose should not exceed a maximum of 40 mg/day in children below 8 years of age. In children over 8 years of age, a maximum daily dosage of 60 mg/day may be given. Baclofen tablets are not suitable for use in children below 33 kg body weight. **Administration:** To be taken during meals with a little liquid. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Peptic ulceration. **Special warnings and precautions for use:** Psychotic disorders, schizophrenia, depressive or manic disorders, confusional

states or Parkinson's disease may be exacerbated by treatment with baclofen. 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. Baclofen may also exacerbate epileptic manifestations. Appropriate supervision and adequate anticonvulsive therapy recommended. Baclofen should be used with extreme care in patients already receiving antihypertensive therapy. Baclofen should be used with caution in patients suffering from cerebrovascular accidents, respiratory or hepatic impairment. A cautious dosage schedule should be adopted in elderly and patients with spasticity of cerebral origin. 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. Particular caution is required when combining baclofen to drugs or medicinal products that can significantly affect renal function. Renal function should be closely monitored and baclofen 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. Under treatment with baclofen 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. 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. 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 baclofen, especially after long term medication. Drug withdrawal reactions including postnatal convulsions in neonates have been reported after intrauterine exposure to oral baclofen. Baclofen should be used with caution when spasticity is needed to sustain upright posture and balance in locomotion. Limited clinical data on the use of baclofen in children < 1 year. Baclofen use should be based on the physician's consideration of individual benefit and risk of therapy. **Interactions:** Levodopa/carbidopa, other muscle relaxants (such as tizanidine), with synthetic opiates or with alcohol, morphine, intrathecal baclofen, tricyclic antidepressants, lithium, anti-hypertensives. Drugs or medicinal products that can significantly affect renal function may reduce baclofen excretion leading to toxic effects. **Pregnancy and lactation:** Baclofen should only be employed if its use is of vital necessity, especially in the first 3 months. The benefits of the treatment for the mother must be carefully weighed against the possible risks for the child. Baclofen crosses the placental barrier. Drug withdrawal reactions including postnatal convulsions in neonates have been reported after intra-uterine exposure to oral baclofen. In mothers taking baclofen at therapeutic doses, the active substance passes into the breast milk, but in quantities so small that no undesirable effects in the infant are to be expected. **Effects on ability to drive and use machines:** Adverse effects such as dizziness, sedation, somnolence and visual impairment may impair the patient's reaction. Patients experiencing these adverse reactions should be advised to refrain from driving or using machines. **Undesirable effects:** For a full list of side effects, consult SmPC. *Very common*

side effects ($\geq 1/10$): sedation, somnolence, nausea. *Common side effects* ($\geq 1/100$ to $< 1/10$): 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, enuresis, dysuria..

Legal Category: Prescription Only Medicine [POM]

Pack quantities and costs: £10.80 per pack of 84 tablets of 5mg tablets, £2.77 per pack of 84 tablets of 20mg tablets

Marketing authorisation holder: Mercury Pharmaceuticals Ltd Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> Adverse events should also be reported to **ADVANZ PHARMA Medical Information** via telephone on **+44 (0) 208 588 9131** via e-mail at medicalinformation@advanzpharma.com