Mylofen™
Baclofen

Presentation
Mylofen™ 5 : Each film coated tablet contains Baclofen BP 5 mg.
Mylofen™ 10 : Each film coated tablet contains Baclofen BP 10 mg.

Description
Baclofen is an effective muscle relaxant and antispastic agent with a spinal site of action. Baclofen is structurally similar to the inhibitory neurotransmitter gamma-amino-butyric acid, though its actions are different. It binds stereospecifically to $GABA_B$ receptors. It is thought that activation of the $GABA_B$ receptors on presynaptic terminal reduces evoked transmitter release, perhaps through reduced presynaptic Ca^{2+} influx. Baclofen can inhibit the function of inward calcium currents in some cells. The drug is rapidly absorbed after oral administration and is widely distributed throughout the body.

Indications
1.The control of spasticity caused by multiple sclerosis and spinal cord lesions.
2.The control of spasticity in children caused by cerebral palsy.
3.The adjunctive management of neurogenic bladder.
4.The management of refractory trigeminal neuralgia.

Dosage and Administrations
The dose should be titrated to gain maximum benefit and minimize adverse reactions.Tablets should be taken with food or milk to reduce gastrointestinal intolerance. Baclofen should be withdrawn gradually if cessation of therapy is indicated. *Adult:* The usual starting dose of Baclofen for adults is 5 mg given three times daily. Based on the response, the dose can be increased gradually every three days by 5 mg to a maximum of 80 mg/day in several doses. It benefits are not evident after a 6 to 8 weeks trial period, patients should be slowly withdrawn from the drug. *Children:* In children aged 12-24 months, the recommended daily dose is10-20 mg, and in children aged 2-10 years, 20-60 mg per day (from starting dose 0.3 -0.75 mg/kg body weight per day up-to 2 mg/kg body weight per day). *Elderly:* Dosages should be cautiously administered and the patient kept under appropriate surveillance. Toxicity due to Baclofen may be mistaken for uraemic encephalopathy. *Impaired Renal Function:* Baclofen should be used with caution. Lower doses (approximately 5 mg per day) should be used for patients with impaired renal function or those undergoing chronic haemodialysis.

Side Effects
seizure (convulsions); confusion, hallucinations; an uneven heartbeat, drowsiness, dizziness, weakness, tired feeling; headache; sleep problems (insomnia); nausea, constipation; urinating more often than usual, rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blurred vision; confusion; frequent urination; increased weakness of arms or legs; seizures; slurred speech; sore throat; vomiting.

Contraindications
Baclofen is contraindicated in epilepsy, spasticity of functional significance, rheumatic muscle spasm and patients who are hypersensitive to any component of this product.

Drug Interaction
Antihypertensives : Baclofen has an occasional hypotensive effect and should be used with care inconjunction with antihypertensive agents. *CNS depressant :*The CNS depressant effects of Baclofen may be additive to those of CNS depressants. *Lithium:* Baclofen may produce severe aggravation of hyperkinetic symptoms in patients receivinglithium.

Precautions
Baclofen should be used with caution in patients who use their spasticity to maintain posture or to increase function. In patient with epilepsy, the clinical state and electroencephalogram should be monitored at regular intervals, since deterioration in seizure control and EEG have been reported occasionally in patient taking Baclofen. Because possibility of sedation, patient should be cautioned regarding the operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness. Patient should be cautioned that the CNS depressant effects of Baclofen may be additive to those of alcohol and other CNS depressants.
Use in pregnancy & lactation: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Baclofen should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In mothers treated with oral Baclofen in therapeutic doses, the active substance passes into the breast milk. Therefore, administration to nursing mothers is not recommended.

Overdosage
Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression, and seizures. Treatment: In the alert patient, empty the stomach promptly by induced emesis followed by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Maintain adequate respiratory exchange, do not use respiratory stimulants.

Pharmaceutical Precautions
Store in a cool and dry place, protected from light.

Commercial Packs
Mylofen™ 5 : Each Box containing 5x10 tablets in blister pack.
Mylofen™ 10 : Each Box containing 5x10 tablets in blister pack.

Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH