Flexilax®

Baclofen BP

COMPOSITION
Flexilax® 5: Each film-coated tablet contains Baclofen BP 5 mg.
Flexilax® 10: Each film-coated tablet contains Baclofen BP 10 mg.

INDICATION
- Spasm
- Reflex muscle contractions
- Indirect effects of treatment with Baclofen include, improved sleep patterns, improvement in bladder and sphincter function and helps in the prevention and healing of decubitus ulcers
- Spasticity resulting from multiple sclerosis
- Spinal cord injuries and other spinal cord diseases
- Muscle spasm of cerebral origin especially infantile cerebral palsy
- Cerebrovascular accidents or neoplastic or degenerative brain disease
- Tension-type headache

PHARMACOLOGIC ACTION
Flexilax® (Baclofen) is an effective muscle relaxant and antispastic agent with a spinal site of action. Its mode of action is not fully understood. **Flexilax®** (Baclofen) inhibits both monosynaptic and polysynaptic reflexes at the spinal level by stimulating the $GABA_B$-receptors, which inhibits the release of glutamate and aspartate. It may also act at intraspinal sites producing CNS depression. Neuromuscular transmission is not affected by Baclofen. **Flexilax®** (Baclofen) also exerts an antinoceptive effect but the clinical significance of this is unknown.

DOSAGE & ADMINISTRATION
Flexilax® (Baclofen) should be taken during meals with a little liquid.

Flexilax® (Baclofen) should be given in divided doses preferably 3 times daily for adults and 4 times daily for children. The lowest dose compatible with an optimal response is recommended.

If benefits are not evident after a 6 to 8 week trial period, patients should be slowly withdrawn from the drug.

Adults:
Start therapy at low dosage and increase gradually until optimum effect is achieved (usually between 30 - 80mg daily).

The following dosage titration schedule is suggested:
5 mg three times a day for 3 days
10 mg three times a day for 3 days
15 mg three times a day for 3 days
20 mg three times a day for 3 days

Thereafter additional increases may be necessary, but the total daily dose should usually not exceed a maximum of 80 mg, although in hospitalised patients daily doses of 100 - 120 mg may occasionally be necessary.

Children:
Treatment should be started at a very low dose e.g. 0.3 mg/kg per day in divided doses. The dosage should be raised cautiously at 1-2 week intervals until it is sufficient for the child's individual needs. The usual dosage range for maintenance therapy is 0.75 to 2 mg/kg body weight per day. In children aged over 10 years a maximum daily dose of 2.5mg/kg bodyweight may be given.

CONTRAINDICATION & PRECAUTION
Known hypersensitivity to Baclofen.
Lower doses (approximately 5 mg per day) should be used for patients with impaired renal function or those undergoing chronic haemodialysis.
Patients suffering not only from spasticity but also from psychotic disorders, schizophrenia, depressive or manic disorders or confusional states should be treated cautiously and closely monitored as exacerbations of these disorders may occur.
In patients with epilepsy and muscle spasticity, Baclofen may be used under appropriate supervision and provided that adequate anticonvulsive therapy is continued. Lowering of the convulsion threshold may occur and seizures have been reported after the cessation of Baclofen therapy or with overdose.
Baclofen should be used with caution in patients with or with a history of peptic ulcers, cerebrovascular diseases, or hepatic, renal or respiratory failure.
Careful monitoring of respiratory and cardiovascular function is essential especially in patients with cardiopulmonary disease and respiratory muscle weakness.
During treatment with Baclofen, neurogenic disturbances affecting emptying of the bladder may improve. However in patients with pre-existing sphincter hypertonia, acute retention of urine may occur. Baclofen should be used with caution in these circumstances.
Baclofen has not significantly benefited patients with stroke. These patients have also shown poor tolerance to the medicine.
Appropriate laboratory tests should be performed periodically in patients with hepatic diseases or diabetes mellitus to ensure that no medicine induced changes in these underlying diseases have occurred.

SIDE EFFECTS
The most common adverse reactions associated with Baclofen are transient drowsiness, daytime sedation, dizziness, weakness and fatigue.
Central Nervous System:
Headache (<10%), insomnia (<10%), and rarely, euphoria, excitement, depression, confusion, hallucinations, paraesthesia, nightmares, muscle pain, tinnitus, slurred speech, co-ordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, miosis, mydriasis, diplopia, dysarthria, epileptic seizures, respiratory depression.
Cardiovascular:
Hypotension (<10%), rare instances of dyspnoea, palpitation, chest pain, syncope.
Gastrointestinal:
Nausea (approximately 10%), constipation (<10%) and rarely, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhoea and positive test for occult blood in stool.
Genitourinary:
Urinary frequency (<10%) and rarely, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, haematuria.
Other:
Instances of rash, pruritus, ankle oedema, excessive perspiration, weight gain, nasal congestion, visual disturbances, hepatic function disorders and paradoxical increase in spasticity.
Muscular hypotonia of a degree sufficient to make walking or movement difficult may occur but is usually relieved by readjusting the dosage. For this purpose, the daytime dosage may be reduced and the evening dosage increased.

USE IN PREGNANCY AND LACTATION
Pregnancy category B3.
Safe use of Baclofen during pregnancy has not been established. Baclofen crosses the placental barrier.
Baclofen should only be administered to pregnant women when in the judgement of the physician concludes that the potential benefits outweigh the possible hazards.
Baclofen is excreted in breast milk however evidence to date suggests that the quantities are so small that no undesirable effects on the infant would be expected.

DRUG INTERACTIONS
Increased sedation may occur if Baclofen is taken with agents acting on the central nervous system, alcohol or synthetic opiates. The risk of respiratory depression is also increased.
Combined treatment with Baclofen and antihypertensives is likely to increase the fall in blood pressure; therefore the dosage of antihypertensive medication should be adjusted accordingly.
The concomitant administration of Baclofen and tricyclic antidepressants may potentiate the pharmacological effects of Baclofen resulting in pronounced muscular hypotonia.
In patients with Parkinsons disease receiving treatment with Baclofen and levodopa and carbidopa, there have been several reports of mental confusion, hallucinations, headaches, nausea and agitation.
The concurrent use of MAO inhibitors and Baclofen may result in increased CNS depressant effects. Caution is advised and the dosage of one or both agents should be adjusted accordingly.
Caution should be exercised when administering Baclofen and magnesium sulphate or other neuromuscular blocking agents since a synergistic effect may theoretically occur.

OVERDOSE
Symptoms of a Baclofen overdose include vomiting, weakness, drowsiness, slow breathing, seizures, unusual pupil size, and coma.

STORAGE
Store in a cool & dry place, protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED
Flexilax® 5 Tablet: Each box contains 30 tablets in blister packing.
Flexilax® 10 Tablet: Each box contains 30 tablets in blister packing.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH