Easybak®

Baclofen BP

Composition:
Easybak®: Each film coated tablet contains Baclofen BP 10 mg.

Indication:
1.Spasm. 2. Reflux muscle contractions.
3. 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.
4. Spasticity resulting from multiple sclerosis. 5. Spinal cord injuries and other spinal cord diseases.
6. Muscle spasm of cerebral origin especially infantile cerebral palsy.
7. Cerebravascular accidents or neoplastic or degenerative brain disease.
8. Tension-Type headache.

Pharmacological Action:
Easybak® (Baclofen) is an effective muscle relaxant and antispastic agent with a spinal site of action. Its mode of action is not fully understood **Easybak®** (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. **Easybak®** (Baclofen) also exerts an antinoceptive effect but the clinical significance of this is unknown.

Dosage and Administration:
Easybak® (Baclofen) should be taken during meals with a little liquid. **Easybak®** (Baclofen) should be given in divided doses preferably 3 times daily for children. The lowest dose compatible with an optimal response is recommended. If benefits are not evident after a 6-8 week trial period, patients should be slowly withdrawn from the drug.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:

5mg three times a day for 3 days	10mg three times a day for 3 days
15mg three times a day for 3 days	20mg 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.0.3mg/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 and precaution:
Known hypersensitivity to Baclofen. Lower doses (approximately 5mg 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.

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, coordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, miosis, mydriasis, diplopia, dysarthria, epileptic seizures, respiratory depression.
Cardivascular :
Hypotension(<10%), rare instances of dysponea, palpitation, chest pain, syncope.

Use in pregnancy and Lactation:
Pregnancy category B3. Safe use of Baclofen is not 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 antihypertensive medication should be adjusted accordingly.

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

Storage :
Store in a cool and dry place, protect from light and moisture. Keep out of the reach of children.

Packaging:
Easybak® Tablet: Each Box contains 3 x 10 tablets in Alu-PVC Blister pack.

Manufactured by
EURO Pharma Ltd.
In Pursuit of Excellence
Dhaka, Bangladesh