



Bacspa-10

Baclofen USP 10 mg Tablet

Composition

Bacspa-10 Tablet : Each film coated tablet contains Baclofen USP 10 mg.

Pharmacology

Baclofen is an effective muscle relaxant and antispastic agent with a spinal site of action. It exerts its action by inhibiting both monosynaptic and polysynaptic transmission in the spinal cord by stimulating GABA-B receptors.

Indication

Bacspa (Baclofen) is indicated for the alleviation of spasticity resulting from multiple sclerosis particularly for the relief of flexor spasm and concomitant pain, clonus and muscular rigidity, spinal cord diseases, muscle spasm of cerebral origin especially infantile cerebral palsy, stroke or neoplastic or degenerative brain diseases. It may be of some value in patients with trigeminal neuralgia, tardive dyskinesia, cluster headache & tension type headache.

Dosage & Administration

Muscle relaxant & spasticity

For adults: Start at a low dosage and increase gradually until the optimum effect is achieved (usually 40-80mg daily). Initially 5 mg three times daily for 3 days; then 10 mg three times daily for 3 days, 15 mg three times daily for 3 days and 20 mg three times daily for 3 days. Additional increases in dose may be required but should not exceed 20 mg four times daily.

For Children: (treatment of spasticity): 0.75-2 mg/kg daily (over 10 years, max. 2.5 mg/kg daily) or 2.5 mg 4 times daily increased gradually according to age to maintenance: 1-2 years 10-20 mg daily, 2-6 years 20-30 mg daily, 6-10 years 30-60 mg daily. Or as directed by the physician.

Contraindication

Baclofen is contraindicated in patients who are hypersensitive to any component of this preparation.

Precaution

Hallucinations and seizures may occur on abrupt withdrawal of Baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued.

Side Effect

Common side effects: Agitation, anxiety, ataxia, cardiovascular depression, confusion, depression, dizziness, drowsiness, dry mouth, euphoria, gastrointestinal disturbances, hallucinations, headache, hypotension, insomnia and myalgia.

Rare side effects: Abdominal pain, changes in hepatic function, paraesthesia and taste disturbances.

Use in pregnancy

There are no adequate and well-controlled studies in pregnant women. So, Baclofen should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation

It is not known whether this drug is secreted in human milk. So, if therapy is considered essential, alternative feeding arrangement should be made.

Use in paediatric patients

Safety and effectiveness in paediatric patients below the age of 12 years have not been established.

Drug Interaction

Anesthetics: Anesthetic agents may potentiate the CNS effects of baclofen.

Antidepressants: The concomitant administration of baclofen and tricyclic antidepressants may potentiate the muscular hypotonia.

Lithium: Concomitant use of oral Baclofen and lithium resulted in aggravated hyperkinetic symptoms.

MAO inhibitors: The concurrent use of MAO inhibitors and Baclofen may result in increased CNS-depressant effects.

Antihypertensives: Since combined treatment with Baclofen and antihypertensives is likely to increase the fall in blood pressure

Levodopa/Dopa Decarboxylase (DDC) inhibitor (carbidopa): In patients with Parkinson's disease receiving treatment with baclofen and levodopa (alone or in combination with a DDC inhibitor, carbidopa), there have been several reports of mental confusion, hallucinations, headache, nausea and agitation.

Antidiabetic agents: Isolated cases of increased blood glucose concentrations have been reported with Baclofen.

Overdose

Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression and seizures.

Storage

Store at temperature below 30° C in a dry place. Protect from light & moisture. Keep out of reach of children.

Packaging

Bacspa-10 Tablet: Each box contains 3X10's tablets in blister pack.



A Syed Manzur Elahi Enterprise

Manufactured by
Apex Pharma Limited
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