
Spafen™

Baclofen

Composition:

Spafen™ 10 Tablet: Each film coated tablet contains Baclofen BP 10 mg.

Description:

Spafen™ 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.

Indications:

Spafen™ 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:

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. Additional increases in dose may be required but should not exceed 20 mg four times daily. Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (20 mg q.i.d.).

Children: 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 for 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.

Side Effects:

Baclofen may cause drowsiness, weakness, dizziness, headache, seizures, nausea, vomiting, low blood pressure, constipation etc.

Precautions:

Because of the possibility of sedation, patients should be

cautioned regarding the operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness. Patients should also be cautioned that the central nervous system effects of Baclofen may be additive to those of alcohol and other CNS depressants.

Baclofen should be used with caution where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain increased function.

In patients 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 patients taking Baclofen.

Use in Pregnancy and Lactation:

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.

Lactation: It is not known whether this drug is excreted in human milk. Caution should be exercised when Baclofen is administered to lactating mother.

Contraindications:

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

Drug Interactions:

The central nervous system depressant effects of Baclofen may be additive to those of alcohol and other CNS depressants.

Storage Condition:

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

Presentation:

Spafen™ 10 Tablet: Each box contains 3X10's tablets in blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.