

Lospan[®]

Baclofen
Tablet

Description

Baclofen is a centrally acting skeletal muscle relaxant and an antispastic agent with a spinal site of action.

Indications

Baclofen is indicated for the signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity, spinal cord injuries and other spinal cord diseases.

Dosage and Method of Administration

The determination of optimal dosage requires individual titration.

The following dosage titration schedule is suggested:

5 mg t.i.d. for 3 days

10 mg t.i.d. for 3 days

15 mg t.i.d. for 3 days

20 mg t.i.d. for 3 days

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.).

The lowest dose compatible with an optimal response is recommended.

Side Effects

The most common side-effects include drowsiness, nausea, dizziness, lightheadedness, confusion, fatigue, muscular pain and weakness, and hypotension. Other side effects include euphoria, hallucinations, depression, headache, tinnitus, convulsions, paresthesias, slurred speech, dry mouth, taste alterations, vomiting, diarrhea or

constipation, ataxia, tremors, insomnia, visual disturbances, skin rashes, urinary disturbances, respiratory or cardiovascular depression, blood sugar changes, alterations in liver function values, and a paradoxical increase in spasticity.

Contraindications

Baclofen is contraindicated in patients with hypersensitivity to any component of this product.

Warning

Abrupt Drug Withdrawal: Hallucinations and seizures have occurred on abrupt withdrawal of baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued.

Impaired Renal Function: Because baclofen is primarily excreted unchanged through the kidneys, it should be given with caution, and it may be necessary to reduce the dosage.

Stroke: Baclofen has not significantly benefitted patients with stroke. These patients have also shown poor tolerability to the drug.

Precautions

Safe use of baclofen in pediatric patients under age 12 has not been established, and it is, therefore, not recommended for use in pediatric patients. 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. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Use in Pregnancy and Lactation

Pregnancy:

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

Lactation:

Baclofen is excreted in breast milk. However, evidence suggests that the quantities are so small that no undesirable effect on the infant would be expected.

Drug Interaction

Alcohol and other CNS depressants may exacerbate the CNS effects of baclofen and should be avoided, severe aggravation of hyperkinetic symptoms may possibly occur in patients taking lithium. There may be increased weakness if baclofen is given to patients taking a tricyclic antidepressant and there may be an increased hypotensive effect if it is given to patients receiving antihypertensive therapy. Ibuprofen and other drugs that produce renal insufficiency may reduce baclofen excretion leading to toxicity.

Pharmaceutical Precautions

Store in cool & dry place, away from children.

Commercial Pack

Lospan[®] 10 tablet: Box containing 30 tablets

in 3 x 10's blister strips. Each tablet contains Baclofen BP 10 mg.

Lospan[®] 25 tablet: Box containing 30 tablets in 3 x 10's blister strips. Each tablet contains Baclofen BP 25 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH

BL 6832

250111

© Lospan is a registered trademark of Beximco Pharmaceuticals Ltd.