

BACLOFEN Tablet Insert

SIZE 140*297

COLORS USED



BACLOFEN

TRILAXANT

10 mg Tablet
Muscle Relaxant

R_x

FORMULATION

Each tablet contains:
Baclofen, USP 10 mg

PRODUCT DESCRIPTION

Yellow, round biconvex tablet with BCL embossed on one side and (S) on the other side.

PHARMACOKINETICS

Baclofen is rapidly and almost completely absorbed from the gastrointestinal tract following an oral dose. Peak plasma concentrations occur about 0.5 to 3 hours after ingestion, but the rate and extent of absorption vary between patients, and may vary inversely with the dose. After oral doses some baclofen crosses the blood-brain barrier, with concentration in CSF about 12% of those in the plasma. Approximately 30% of baclofen is bound to plasma proteins. About 70 to 80% of a dose is excreted in the urine mainly as unchanged drug; about 15% is metabolized in the liver. The elimination half-life of baclofen is about 3 to 4 hours in plasma and about 1 to 5 hours in the CSF. Baclofen crosses the placenta and is distributed into breast milk.

PHARMACODYNAMICS

Baclofen is an antispastic agent acting at the spinal level. A gamma-aminobutyric acid (GABA) derivative, chemically unrelated to other antispastic agents. Baclofen depresses monosynaptic and polysynaptic reflex transmission, probably by stimulating the GABA β -receptors. This stimulation in turn inhibits the release of the excitatory amino acids glutamate and aspartate. Neuromuscular transmission is unaffected by baclofen. The major benefits of baclofen stem from its ability to reduce painful flexor spasms and spontaneous clonus thereby facilitating the mobility of the patient, increasing their independence and helping rehabilitation. Baclofen also exerts an antinociceptive effect. General well being is often improved and sedation is less often a problem than with centrally acting drugs. Baclofen stimulates gastric acid secretion.

INDICATIONS

Baclofen is commonly used for the symptomatic relief of severe chronic spasticity associated with a variety of conditions. It is used to reduce muscle spasm and pain especially in spinal cord lesions in conditions such as multiple sclerosis or paraplegia. It is also used for spasticity of cerebral origin.

DOSAGE AND ROUTE OF ADMINISTRATION

Baclofen is given by mouth in divided doses, preferably with or after food or milk. The initial dose of baclofen is 5 mg three times daily for 3 days, increased to 10 mg three times daily for 3 days, then in similar increments and intervals until either a dose of 20 mg three times daily is reached or until the desired therapeutic effect is obtained. Higher doses have been used. Doses of more than 80 to 100 mg daily are not generally recommended although doses of up to 150 mg daily have been given to carefully supervised patients. In children over 10 years a maximum daily dosage of 2.5 mg/kg may be given. It is usual to start with a low dose of 2.5 mg given four times daily, increased cautiously about every 3 days until the desired therapeutic effect is obtained. The recommended daily maintenance doses are: 12 months to 2 years, 10 to 20 mg; 2 to 6 years, 20 to 30 mg; 6 to 10 years, 30 to 60 mg. Elderly patients should receive lower initial doses, although final maintenance doses may be in the same range as younger adults. Doses of baclofen should be reduced in renal impairment or in patients undergoing chronic hemodialysis 5 mg daily by mouth has been suggested. If no benefit is apparent within 6 weeks of achieving the maximum dosage, therapy should probably be gradually withdrawn. Or as prescribed by the physician.

CONTRAINDICATIONS

Hypersensitivity to baclofen or to any of the excipients.
Peptic ulceration.

PRECAUTIONS

Baclofen stimulates gastric acid secretion and should be used with caution in patients with a history of peptic ulcer and avoided in those with active peptic ulcer disease. It should also be used with caution in patients with severe psychiatric disorders or epilepsy or convulsive disorders since these disorders may be exacerbated by baclofen. Liver function should be monitored in patients with liver disease; patients with renal impairment need a reduced dose. Baclofen should be used with caution in patients with respiratory impairment. Observations of increased blood sugar concentrations suggest caution in patients with diabetes mellitus. Care is also required in the elderly, in whom adverse effects may be more common, and in patients with cerebrovascular disease (who tolerate baclofen poorly). It should be used with caution in patients who use their spasticity to maintain posture or to increase function. Urine retention may be exacerbated in patients with hypertonic bladder sphincters. Baclofen may cause drowsiness; patients affected should not drive or operate machinery. Abrupt withdrawal of baclofen may result in a withdrawal syndrome and exacerbation of spasticity; dosage should be reduced gradually over at least 1 to 2 weeks or longer if symptoms occur.

ADVERSE EFFECTS

The most common side-effects include drowsiness, nausea, dizziness, lassitude, lightheadedness, confusion, fatigue, muscular pain and weakness, and hypotension. Other side-effects include euphoria, hallucinations, depression, headache, tinnitus, convulsions, paraesthesias, slurred speech, dry mouth, taste alterations, vomiting, diarrhea or constipation, ataxia, nystagmus, tremors, insomnia, visual disturbances, skin rashes, pruritus, increased sweating, urinary disturbances, respiratory or cardiovascular depression, blood sugar changes, alterations in liver function values, and a paradoxical increase in spasticity.

INTERACTIONS

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.

OVERDOSE AND TREATMENT

Overdosage may lead to muscular hypotonia, drowsiness, respiratory depression, coma, and convulsions. Treatment of overdosage is symptomatic. Consideration should be given to gastric lavage and/or the use of activated charcoal in patients who have ingested more than 100 mg within an hour of presentation; activated charcoal is recommended

in children who have taken more than 5 mg/kg or 100 mg within the last hour. Observation should continue for at least 6 hours after ingestion. Atropine sulfate 600 micrograms intravenously was used to treat a patient who had ingested 420 mg of baclofen and had failed to improve after gastric lavage and induced diuresis.

FERTILITY, PREGNANCY AND LACTATION

Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Limited information indicates that orally administered baclofen appears in low levels in milk and would not be expected to cause any adverse effects in breast-fed infants, especially if the infant is older than 2 months. Monitor newborn infants for signs of sedation. Low intrathecal doses and topical application produce even lower milk levels and are unlikely to affect the nursing infant.

STORAGE CONDITION

Store at temperatures not exceeding 25°C.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at first sign of any adverse drug reaction.

AVAILABILITY

Alu/PVC Blister Pack x 10's (Box of 100's)

Registration Number: DR-XY35815

Date of First Authorization: 29 February 2012

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