Restobac

Baclofen Tablet

Presentation

RESTOBAC 10: Each tablet contains Baclofen BP 10 mg.

Indications

RESTOBAC is useful for the alleviation of signs and symptoms of spasticity. RESTOBAC is indicated for:

- Spasm • Spasticity of skeletal muscles in multiple sclerosis • Spastic conditions occuring in spinal cord diseases • Tension type headache • Muscle spasm of cerebral origin, especially infantile cerebral palsy
- Cerebrovascular accidents, neoplastic, degenerative brain diseases • Syringomyelia, transverse myelitis, traumatic paraplegia, spastic spinal paralysis • Flexor spasms and concomitant pain • Back pain

Pharmacodynamic Properties

Baclofen is an antispastic agent acting at the spinal level. A gamma-aminobutyric acid (GABA) derivative, Baclofen is chemically unrelated to other antispastic agents. Baclofen depresses monosynaptic and polysynaptic reflex transmission, probably by stimulating the GABAB-receptors, this stimulation in turn inhibiting the release of the excitatory amino acids glutamate and aspartate. Baclofen also exerts an antinociceptive effect.

Pharmacokinetic Properties

Absorption: Baclofen is rapidly and completely absorbed from the gastro-intestinal tract. Following oral administration of single doses (10-30mg) peak plasma concentrations are recorded after 0.5 to 1.5 hours.

Distribution: The volume of distribution of Baclofen is 0.7 L/kg and the protein binding rate is approximately 30%.

Biotransformation: Baclofen is metabolized to only a minor extent. De-amination yields the main metabolite, ß-(p-chlorophenyl)-4-hydroxybutyric acid, which is pharmacologically inactive.

Elimination/Excretion: The plasma elimination half-life of Baclofen averages 3 to 4 hours.

Dosage and administration:

Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 to 80 mg daily). The following dosage titration schedule is suggested:

Adults: 5 mg t.i.d. for 3 days; 10 mg t.i.d. for next 3 days; 15 mg t.i.d. for next 3 days; 20 mg t.i.d. for next 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.).

Elderly: Small doses should be used at the start of treatment, the dose being titrated gradually against the response, under careful supervision.

Children: A dosage range of 0.75-2mg/kg body weight should be used. In children over 10 years of age, however a maximum daily dosage of 2.5mg/kg body weight may be given. Treatment is usually started with 2.5mg given 4 times daily. The dosage should be cautiously raised at about 3 day intervals, until it becomes sufficient for the child's individual requirements. The recommended daily dosages for maintenance therapy are as follows:

- 12 months - 2 years : 10-20mg • 2 years - 6 years : 20-30mg • 6 years - 10 years : 30-60mg

Patients with impaired renal function

In patients with impaired renal function or undergoing chronic haemodialysis, a particularly low dosage of Baclofen should be selected i.e. approx. 5mg daily.

Contraindications

Restobac tablet is contraindicated in patients with hypersensitivity to Baclofen or any excipients of this tablet. Also contraindicated in case of Peptic Ulcer.

Precautions

Psychotic disorders, schizophrenia, depressive or manic disorders, confusional states or Parkinson's disease may be exacerbated by treatment with Baclofen.

Abrupt withdrawal: Anxiety and confusional states, hallucinations, psychotic, manic or paranoid states, convulsions (status epilepticus), dyskinesia, tachycardia, hyperthermia and as rebound phenomenon temporary aggravation of spasticity have been reported with abrupt withdrawal of Baclofen, especially after long term medication. Treatment should always, (unless serious adverse effects occur), therefore be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks.

Drug Interactions

Where Baclofen is taken concomitantly with other drugs acting on the CNS, with synthetic opioid or with alcohol, increased sedation may occur. The risk of respiratory depression is also increased. Careful monitoring of respiratory and cardiovascular functions is essential especially in patients with cardiopulmonary disease and respiratory muscle weakness. During concurrent treatment with TCA, the effect of Baclofen may be potentiated. Since concomitant treatment with Baclofen and anti-hypertensives is likely to increase hypotension, the dosage of antihypertensive medication should be adjusted accordingly.

Use in Pregnancy and Lactation

Pregnancy category C. The benefits of the treatment for the mother must be carefully weighed against the possible risks for the child. Baclofen crosses the placental barrier. In mothers taking Baclofen in therapeutic doses, the active substance passes into the breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

Side Effects

Unwanted effects occur mainly at the start of treatment (e.g. sedation, somnolence and nausea), if the dosage is raised too rapidly, if large doses are employed, or in elderly patients. Should nausea persist following a reduction in dosage, it is recommended that Baclofen be ingested with food or a milk beverage. Unlikely to occur clinical events include mental/mood changes, seizures, vision changes, muscle stiffness, stomach pain, vomiting, trouble breathing, painful urination, change in urine amount. Very unlikely events are impotence, chest pain, black stools, fainting, and unsteadiness.

Overdose

Prominent features are signs of central nervous depression, coma generalized muscular hypotonia, myoclonia, hyporeflexia or areflexia; convulsions; peripheral vasodilatation, hypotension, bradycardia; hypothermia; nausea, vomiting, diarrhoea, hypersalivation.

Treatment of Overdose

No specific antidote is known. Gastric decontamination (e.g. gastric lavage) should be considered in individual cases, especially in the early period (60 minutes) after ingestion of a potentially life-threatening overdose.

Storage Conditions

Store in a cool and dry place. Protect from light and moisture. Keep all medicines out of the reach of children.

Commercial Pack

RESTOBAC 10: Each box contains 3 blister packs of 10 tablets.

Manufactured by :
GENERAL Pharmaceuticals Ltd.
Gazipur, Bangladesh