

Reflexen

Baclofen
10 mg & 25 mg Tablet

Reflexen (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 Gamma Amino Butyric Acid (GABA) receptors.

COMPOSITION

Reflexen 10 Tablet : Each tablet contains Baclofen USP 10 mg.

Reflexen 25 Tablet : Each tablet contains Baclofen USP 25 mg.

INDICATION

Reflexen (Baclofen) is indicated for the alleviation of spasticity resulting from multiple sclerosis particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity, spinal cord diseases, muscle spasm of cerebral organ especially infantile cerebral palsy, stroke or neoplastic of degenerative brain diseases.

DOSAGE AND ADMINISTRATION

Adults :

Initially 5 mg 3 times daily for 3 days; then 10 mg 3 times daily for 3 days, 15 mg 3 times daily for 3 days, 20 mg 3 times daily for 3 days and 25 mg 3 times daily for 3 days. Additional increases may be necessary; in that case optimum dosage generally ranges from 30 - 80 mg daily in 3 - 4 equally divided doses but should not exceed 80 mg daily.

Children :

Generally, dosage in the range of 0.75 mg to 2.0 mg/kg body weight should be given. In children over 10 years of age, a maximum daily dosage of 2.5 mg/kg body weight may be given in 4 equally divided doses.

Maintenance therapy:

Children aged 12 months to 2 years : 10 to 20 mg.

Children aged 2 to 6 years : 20 to 30 mg.

Children aged 6 to 10 years : 30 to 60 mg.

SIDE EFFECT

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

PRECAUTION

Hallucinations and seizures may occur on sudden withdrawal of Baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is to be discontinued. Elderly patients are more likely to have decreased renal function; thus care should be taken in dose selection. Moreover, it may be necessary to reduce the dosage in patients with impaired renal function.

CONTRAINDICATION

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

DRUG INTERACTION

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

USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Baclofen is C. 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 risk to the fetus. It is not known whether this drug is excreted in to the breast milk. So, if therapy is considered essential, alternative feeding arrangement should be made for the child.

STORAGE CONDITION

Keep in a dry place away from light and heat. Keep out of the reach of children.

HOW SUPPLIED

Reflexen 10 Tablet : Each box contains 30 tablets in Alu-PVDC blister pack.

Reflexen 25 Tablet : Each box contains 30 tablets in Alu-PVDC blister pack.

Manufactured by:

NIPRO JMI Pharma Ltd.
Comilla, Bangladesh.