Fenobac®

Baclofen USP tablet and syrup

DESCRIPTION

Fenobac® is the preparation of Baclofen. Baclofen is an effective muscle relaxant and antispastic agent with a spinal site of action. Baclofen is structurally similar to the inhibitory neurotransmitter gamma-amino-butyric acid, though its actions are different. It binds stereospecifically to $GABA_B$ receptors. It is thought that activation of the $GABA_B$ receptors on presynaptic terminal reduces evoked transmitter release, perhaps through reduced presynaptic Ca^{2+} influx. Baclofen can inhibit the function of inward calcium currents in some cells. The drug is rapidly absorbed after oral administration and is widely distributed throughout the body.

INDICATIONS

1. The control of spasticity caused by multiple sclerosis and spinal cord lesions.
2. The control of spasticity in children caused by cerebral palsy.
3. The adjunctive management of neurogenic bladder.
4. The management of refractory trigeminal neuralgia.

DOSAGE AND ADMINISTRATION

- The dose should be titrated to gain maximum benefit and minimize adverse reactions.
- Tablets should be taken with food or milk to reduce gastrointestinal intolerance.
- Baclofen should be withdrawn gradually if cessation of therapy is indicated.

Fenobac® Tablet:

Adult: The usual starting dose of Baclofen for adults is 5 mg given three times daily. Based on the response, the dose can be increased gradually every three days by 5 mg to a maximum of 80 mg/day in several doses. If benefits are not evident after a 6 to 8 weeks trial period, patients should be slowly withdrawn from the drug.

Children: In children aged 12-24 months, the recommended daily dose is 10-20 mg, and in children aged 2-10 years, 20-60 mg per day (from starting dose 0.3 -0.75 mg/kg body weight per day up-to 2 mg/kg body weight per day).

Elderly: Dosages should be cautiously administered and the patient kept under appropriate surveillance. Toxicity due to Baclofen may be mistaken for uraemic encephalopathy.

Impaired Renal Function: Baclofen should be used with caution. Lower doses (approximately 5 mg per day) should be used for patients with impaired renal function or those undergoing chronic haemodialysis.

Fenobac® Syrup:

Adult: In adult the usual dose is 20 mL three times a day.

Children: A dosage of 0.75- 2 mg/ kg body weight should be used. In children over ten years of age, however a maximum daily dosage of 2.5 mg/ kg body weight may be given. Treatment is usually started with half a 5 ml spoonful (2.5 mg) given four times daily. The dosage should be cautiously raised at about three day intervals, until it becomes sufficient for the child's individual requirements. The recommended daily dosages for maintenance therapy are as follows:

Children aged: 12 months- 2 years: 10 mL- 20 mL
2 years- 6 years: 20 mL- 30 mL
6 years- 10 years: 30 mL- 60 mL

CONTRAINDICATIONS

Baclofen is contraindicated in epilepsy, spasticity of functional significance, rheumatic muscle spasm and patients who are hypersensitive to any component of this product.

ADVERSE REACTIONS

Common adverse reactions include sedation, lethargy, vertigo, headache, nausea and diarrhea. Other infrequent side-effects are muscular hypotonia, urinary disturbances, confusion, speech disturbance, ataxia, hallucination, nightmares, euphoria, insomnia, depression, anxiety, agitation, tremor, nystagmus, paraesthesias, seizures, myalgia, fever, respiratory or cardiovascular depression, hypotension, dry mouth, gastrointestinal disorder, sexual dysfunction, visual disorders, rash, pruritis, urticaria, hyperhidrosis, angioedema, rarely taste alterations, blood sugar changes and paradoxical increase in spasticity. Some of the CNS and genitourinary symptoms may be related to the underlying disease rather than to drug therapy.

PRECAUTIONS

Baclofen should be used with caution in patients who use their spasticity to maintain posture or to increase function. In patient 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 patient taking Baclofen. Because of possibility of sedation, patient should be cautioned regarding the operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness. Patient should be cautioned that the CNS depressant effects of Baclofen may be additive to those of alcohol and other CNS depressants.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Baclofen should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In mothers treated with oral Baclofen in therapeutic doses, the active substance passes into the breast milk. Therefore, administration to nursing mothers is not recommended.

DRUG INTERACTIONS

a) Antihypertensives - Baclofen has an occasional hypotensive effect and should be used with care in conjuction with antihypertensive agents.
b) CNS depressant - The CNS depressant effects of Baclofen may be additive to those of CNS depressants.
c) Lithium - Baclofen may produce severe aggravation of hyperkinetic symptoms in patients receiving lithium.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Fenobac® 5 Tablets	: Box containing 5 strips of 10 tablets each. Each tablet contains Baclofen USP 5 mg.
Fenobac® 10 Tablets	: Box containing 3 strips of 10 tablets each. Each tablet contains Baclofen USP 10 mg.
Fenobac® Syrup	: Bottle containing 100 mL syrup. Each 5 mL contains Baclofen USP 5 mg.

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Manufactured by
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