Liorel®

Baclofen

Description

Liorel® is the preparation of Baclofen which is an effective muscle relaxant and antispastic agent. It inhibits both monosynaptic and polysynaptic reflexes at the spinal level by stimulating the $GABA_B$ receptors, which inhibits the release of glutamate and aspartate. 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 current in some cells. It may also act at intraspinal sites producing CNS depression. Neuromuscular transmission is not affected by Baclofen. It also exerts an antinociceptive effect.

Indications

Liorel® is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions e.g., tumours of the spinal cord, syringomyelia, motor neuron disease, transverse myelitis and spinal cord injuries.

Liorel® is also indicated in adults and children for the relief of spasticity of voluntary muscle arising from e.g, cerebrovascular accidents, cerebral palsy, meningitis and traumatic head injury.

Dosage and administration

Adult: The determination of optimal dosage requires individual titration.The usual initial dose of **Liorel®** is 5 mg 3 times daily. Based on the response, the dose can be increased gradually until optimum effect is achieved (usually between 40 to 80 mg daily).

The following dosage titration schedule is suggested:

- 5 mg three times a day for 3 days
- 10 mg three times a day for 3 days
- 15 mg three times a day for 3 days
- 20 mg three times a day 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 four times daily).

Children: Treatment should be started at a very low dose of 0.75 mg/kg per day in divided doses. In children over 10 years of age maximum 2.5 mg/kg per day should be given. Treatment is usually started with 2.5 mg 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:

Children aged:

- 1 to 2 years: 10-20 mg daily
- 2 to 6 years: 20-30 mg daily
- 6 to 10 years: 30-60 mg daily

Elderly: Elderly patients may be more susceptible to side effects, particularly in the early stages of introducing **Liorel®**. Small doses should therefore be used at the start of treatment, the dose being titrated gradually against the response, under careful supervision. There is no evidence that the eventual average maximum dose differs from that in younger patients.

Patients with renal impairment: In patients with impaired renal function or undergoing chronic haemodialysis, a particularly low dosage of **Liorel®** should be selected i.e. approximately 5 mg daily.

Patients with spastic states of cerebral origin: Unwanted effects are more likely to occur in these patients. It is therefore recommended that a very cautions dosage schedule be adopted and that patients be kept under appropriate surveillance.

Use in pregnancy & lactation

The safety of Baclofen in women who are or who may become pregnant has not been established. Baclofen should be used during pregnancy only if the potential benefit clearly justifies the potential risk to the fetus. 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

The most common side effects are gastro-intestinal disturbances, dry mouth, hypotension, respiratory or cardiovascular depression, sedation, drowsiness, confusion, dizziness, ataxia, hallucinations, nightmares, headache, euphoria, insomnia, depression, anxiety, agitation, tremor, seizure, urinary disturbances, myalgia, nystagmus, visual disorders, rash, hyperhidrosis, rarely taste disturbances, abdominal pain, erectile dysfunction, dysarthria and very rarely hypothermia.

Contraindications

Baclofen is contraindicated in patients with hypersensitivity to Baclofen or to any of the excipients. It is also contraindicated in peptic ulcer diseases.

Precautions

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. 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 bean reported occasionally in patient taking Baclofen. Patient should be cautioned that the CNS depressant effects of Baclofen may be additive to those of alcohol and other CNS depressants.

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Drug interactions

During concurrent treatment with tricyclic antidepressants, the effect of Baclofen may be potentiated, resulting in pronounced muscular hypotonia. Since concomitant treatment with Baclofen and anti-hypertensives is likely to increase the fall in blood pressure, the dosage of antihypertensive medication should be adjusted accordingly. In patients with Parkinson's disease receiving treatment with Baclofen and levodopa plus carbidopa, there have been reports of mental confusion, hallucinations, nausea and agitation. Drugs or medicinal products that can significantly affect renal function may reduce Baclofen excretion leading to toxic effects.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Presentation

Liorel® 5 tablet: Each tablet contains Baclofen USP 5 mg.
Liorel® 10 tablet: Each tablet contains Baclofen USP 10 mg.

Package quantities

Liorel® 5 tablet: Carton of 50 tablets in blister.
Liorel® 10 tablet: Carton of 30 tablets in blister.

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