

# Bacifen

Baclofen

## Composition

Bacifen 10 mg Tablet: Each film-coated tablet contains Baclofen BP 10 mg.

## Indication

Spasm

Reflex muscle contractions

Indirect effects of treatment with Baclofen include, improved sleep patterns, improvement in bladder and sphincter function and helps in the prevention and healing of decubitus ulcers

Spasticity resulting from multiple sclerosis

Spinal cord injuries and other spinal cord diseases

Muscle spasm of cerebral origin especially infantile cerebral palsy

Cerebrovascular accidents or neoplastic or degenerative brain disease

Tension-type headache

## Pharmacology

Bacifen (Baclofen) is an effective muscle relaxant and antispasmodic agent with a spinal site of action. Its mode of action is not fully understood. Bacifen (Baclofen) inhibits both monosynaptic and polysynaptic reflexes at the spinal level by stimulating the GABAB-receptors, which inhibits the release of glutamate and aspartate. It may also act at intraspinal sites producing CNS depression. Neuromuscular transmission is not affected by Baclofen. Bacifen (Baclofen) also exerts an antinoceptive effect but the clinical significance of this is unknown.

## Dosage & Administration

Bacifen (Baclofen) should be taken during meals with a little liquid.

Bacifen (Baclofen) should be given in divided doses preferably 3 times

daily for adults and 4 times daily for children. The lowest dose compatible with an optimal response is recommended.

If benefits are not evident after a 6 to 8 week trial period, patients should be slowly withdrawn from the drug.

## Adults:

Start therapy at low dosage and increase gradually until optimum effect is achieved (usually between 30 - 80mg 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 usually not exceed a maximum of 80 mg, although in hospitalised patients daily doses of 100 - 120 mg may occasionally be necessary.

## Children:

Treatment should be started at a very low dose e.g. 0.3 mg/kg per day in divided doses. The dosage should be raised cautiously at 1-2 week intervals until it is sufficient for the child's individual needs. The usual dosage range for maintenance therapy is 0.75 to 2 mg/kg body weight per day. In children aged over 10 years a maximum daily dose of 2.5mg/kg bodyweight may be given.

## Contraindication & Precaution

Known hypersensitivity to Baclofen. Lower doses (approximately 5 mg per day) should be used for patients with impaired renal function or those undergoing chronic haemodialysis.

## Side Effects

The most common adverse reactions associated with Baclofen are transient drowsiness, daytime sedation, dizziness, weakness and fatigue.

## Use In Pregnancy And Lactation

Pregnancy category B3. Safe use of Baclofen during pregnancy has not been established.

## Drug Interactions

Increased sedation may occur if Baclofen is taken with agents acting on the central nervous system, alcohol or synthetic opiates. The risk of respiratory depression is also increased.

## Overdose

Symptoms of a Baclofen overdose include vomiting, weakness, drowsiness, slow breathing, seizures, unusual pupil size, and coma.

## Storage

Store in a cool & dry place, protect from light & moisture. Keep out of the reach of children.

## Commercial Pack

**Bacifen 10 mg Tablet:** Each box contains 30 tablets in blister pack.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.