# Spinafen Baclofen BP

**Presentation Spinafen 10 tablet:** Each tablet contains Baclofen BP 10 mg

# Description

Baclofen is centrally acting skeletal muscle relaxant and an anti-spastic agent with a spinal site of action. It exerts its effects as an agonist at presynaptic  $GABA_B$  receptors mainly at the spinal cord level to inhibit the transmission of both monosynaptic and polysynaptic reflexes, possibly by hyperpolarization of primary afferent fiber terminals, resulting in antagonism of the release of putative excitatory transmitters (i.e., glutamic and aspartic acids).

# Indication

**Spinafen** is indicated for the relief of spasticity of voluntary muscle particularly flexor spasms, concomitant pain, muscle clonus, and muscular rigidity arising from multiple sclerosis, cerebrovascular accidents, traumatic head injury, cerebral palsy or degenerative brain disease.

It is also indicated in spinal cord injuries and other spinal cord diseases

## **Dosage and Administrations**

**Spinafen** should be taken during meal with a little liquid *Adults*:

Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40-80 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

Daily doses of 100-120 mg may be given to carefully supervised patients in hospitals. If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug.

## Children:

Treatment usually commences with 2.5 mg 4 times a day. A dosage range of 0.75 to 2 mg/kg body weight should be used. In children over 10 years of age, a maximum daily dosage of 2.5 mg/kg body weight may be given.

## Patients with renal impairment

Baclofen is primarily excreted unchanged by the kidneys. It should be given with caution and it may be necessary to reduce the dosage in patients with impaired renal function.

## Side effect

Baclofen may cause drowsiness, weakness, dizziness, headache, seizures, nausea, vomiting, low blood pressure, constipation, confusion, respiratory depression, and inability to sleep. Abrupt discontinuation of oral Baclofen may cause seizures and hallucinations

## Contraindication

Peptic ulceration and hypersensitivity to Baclofen

## Precaution

Psychotic disorders, confusional states, schizophrenia, depressive or manic disorders or Parkinson's disease should be treated cautiously with Baclofen. . Caution should be exercised with its therapy in patients suffering from renal, hepatic or respiratory impairment or who have had a cerebro-vascular accident & patients already receiving antihypertensive therapy. Patients taking Baclofen should not operate vehicles, other means of transport, or machinery where loss of attention may lead to accidents.

## Use in pregnancy and lactation

This medication should be used only when clearly needed during pregnancy where treatment is necessary, the benefits for the mother should be carefully considered against the possible risks to the fetus. Baclofen should only be used if essential and not recommended during lactation as it is secreted in breast milk.

#### **Drug interaction**

Hallucination, agitation, and mental confusion have been reported by use of Baclofen with levodopa and carbidopa in Parkinson's disease. Use of tricyclic antidepressant and Baclofen may result in the potentiation of the effect of Baclofen, resulting in pronounced muscular hypotonia. Concomitant use of drugs acting on the CNS or alcohol with Baclofen may lead to increased sedation.

#### Overdosage

Primarily central nervous system depression occurs. No specific antidote is known. If vomiting or gastric lavage is induced, drug in stomach can be removed. In that case, activated charcoal or saline aperient may be given.

#### **Storage:**

Store it in a cool and dry place. Spinafen should be stored between 15  $^{0}$ C (59  $^{0}$ F) and 30  $^{0}$ C

## **Commercial pack**

Spinafen 10 tablet: Each box contains scored, round 3x10 tablets in blister pack.