

# BACOFEN

## BACLOFEN

### **Compositions:**

Bacofen 5 Tablet: Each film coated tablet contains Baclofen BP 5 mg. Bacofen 10 Tablet: Each film coated tablet contains Baclofen BP 10 mg.

### **Pharmacology:**

Baclofen is an effective muscle relaxant and antispastic agent with a spinal site of action. Its mode of action is not fully understood. 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. Baclofen also exerts antinociceptive effect. Indication: Baclofen is indicated for

### **Dosage And Administration:**

Adult The initial dose of baclofen is 5 mg three times daily by mouth preferably with or after food or milk-The total daily dose is increased by 15 mg every fourth day (i.e. the dosage regimen is 5 mg 3 times a day for 3 days, then 10 mg 3 times a day for 3 days, then 15 mg 3 times a day for 3 days), until either a dose of 20 mg three times a day is reached or until the desired therapeutic effect is obtained. Children: The usual dosage range for children is 0.75 to 2 mg/kg body weight per day. In children aged over 10 years a maximum daily dose of 2.5 mg/kg body weight may be given. The usual starting dose is 2.5 mg given four times daily increased cautiously about every three days until the desired therapeutic effect is obtained. The recommended daily maintenance doses are: 12 months to 2 years of age, 10 to 20 mg; 2 to 6 years, 20 to 30 mg; 6 to 10 years, 30 to 60 mg.

### **Contraindications:**

Baclofen is contraindicated in patients who are hypersensitive to any component of this product.

### **Warning And Precaution:**

Baclofen stimulates gastric acid secretion and should be used with caution in patients with a history of peptic ulcer and avoided in those with active peptic ulcer disease, Liver function should be monitored in patients with liver disease, patients with renal impairment need a reduced dose. Baclofen should be used with caution in patients with respiratory impairment. Baclofen may cause drowsiness, patients affected should not drive or operate machinery.

### **Side Effects:**

The most common side effects include day time drowsiness, sedation, lethargy, dizziness, headache, nausea and diarrhea. Other infrequent side-effects are muscular hypotonia, urinary disturbances, confusion, speech disturbance, insomnia, depression, anxiety, agitation, myalgia, fever, respiratory depression, hypotension, dry mouth, sexual dysfunction, visual disorders, rash, pruritis, weight gain, taste alterations, blood sugar changes.

### **Use in Pregnancy and Lactation:**

The safety of baclofen in women who are or who may become pregnant has not been established. Baclofen crosses the placental barrier. Baclofen should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Baclofen is excreted in breast milk however evidence to date suggests that the quantities are so small that no undesirable effects on the infant would be expected.

**Drug Interaction:**

Alcohol and other CNS depressants may exacerbate the CNS effects of baclofen and should be avoided, severe aggravation of hyperkinetic symptoms may possibly occur in patients taking lithium, Ibuprofen and other drugs that produce renal insufficiency may reduce baclofen excretion leading to toxicity.

**Overdosage:**

If you have accidentally taken many more tablets than your doctor has prescribed, seek immediate emergency medical treatment, even though you do not feel sick. The main symptoms of overdose are drowsiness, breathing difficulties, trouble of consciousness and being unconscious (coma). Other symptoms may include: feeling confused, hallucinations, agitation, convulsions, blurred vision, unusual muscle weakness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow, fast or irregular heart beat, low body temperature, nausea, vomiting, diarrhea or excessive salivation, trouble breathing during sleep (sleep apnoea), pain in muscles, fever and dark urine (rhabdomyolysis). If you have kidney disease and have accidentally taken more tablets or more syrup than your doctor has prescribed, you may experience neurological symptoms of overdose (e.g. drowsiness, feeling confused, hallucinations).

**Storage:**

Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

**Packing:**

Bacofen 5 Tablet: Each box contains 5x10 tablets of baclofen BP 5 mg in blister packing.  
Bacofen 10 tablet: Each box contains 3x10 tablets of baclofen BP 10 mg in blister packing.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.  
Shafipur, Gazipur, Bangladesh.