

Bacloable 10 Tablet

Baclofen (10 mg) Tablet: Product Information

Brand Name: Baclofen 10 mg Tablet

Generic Name: Baclofen

Strength: 10 mg per tablet

Dosage Form: Oral Tablet

Indications:

Baclofen 10 mg tablet is a **muscle relaxant** that is used to treat conditions involving **muscle spasticity** and related symptoms. It is indicated for:

- Muscle Spasticity:**
 - Treatment of **spasticity** caused by **neurological conditions** such as **multiple sclerosis, spinal cord injuries, spinal diseases, and cerebral palsy**.
 - Baclofen helps relieve **muscle stiffness** and reduces the frequency and intensity of muscle spasms.
- Neurological Disorders:**
 - Used to manage **muscle spasms** and associated pain in **spinal cord injuries, stroke, and cerebral palsy**.
- Relief of Muscle Stiffness:**
 - It helps with the **relaxation of muscle tone**, improving mobility and reducing discomfort caused by conditions that cause muscle spasms.

Mechanism of Action:

Baclofen is a **GABA-B receptor agonist** that primarily acts on the **central nervous system (CNS)**. It works by binding to **GABA-B receptors** in the **spinal cord**, which inhibits the release of **excitatory neurotransmitters**, resulting in **reduced muscle spasticity** and **muscle relaxation**. By dampening nerve activity, Baclofen helps to reduce involuntary muscle contractions.

Dosage and Administration:

Adults:

- Starting Dose:** The usual initial dose is **5 mg**, taken **3 times a day**. The dose can be gradually increased depending on tolerance.
- dose** is typically **80 mg** in divided doses, but this may vary based on individual circumstances.
- Dose Titration:** The dose may be increased in increments of **5 mg to 10 mg** every **3-7 days**, as tolerated, to minimize side effects.

Pediatric Use:

- Baclofen is sometimes used in children for **spasticity**. The starting dose for children is usually around **0.3 mg/kg/day**, which is divided into smaller doses.
- The dose may be increased gradually based on the child's response to treatment.

Administration:

- Take Baclofen 10 mg tablet** with or without food, as directed by your healthcare provider.
- Swallow the tablet **whole** with a glass of water.
- Do not stop taking Baclofen suddenly or adjust the dose without consulting your healthcare provider, as this may lead to withdrawal symptoms or a worsening of muscle spasticity.

Contraindications:

Baclofen should not be used in the following conditions:

- Hypersensitivity** (allergic reactions) to Baclofen or any of its components.
- Severe renal impairment** or kidney dysfunction, as Baclofen is primarily excreted through the kidneys.
- Active peptic ulcer disease** or history of significant gastrointestinal bleeding.

Warnings and Precautions:

- **CNS Depression:** Baclofen can cause **drowsiness, dizziness, and sedation**, especially at higher doses. Use caution when engaging in activities that require full alertness, such as driving or operating machinery.
- **Withdrawal Symptoms:** Abrupt discontinuation or rapid dose reduction of Baclofen can lead to **withdrawal symptoms** such as **seizures, hallucinations, delirium, and increased spasticity**. Tapering the dose gradually is essential when discontinuing treatment.
- **Hypotension:** Baclofen may cause a decrease in **blood pressure**, especially in older patients or those taking blood pressure medications.
- **Liver Disease:** Use Baclofen with caution in patients with **liver conditions**, as the drug may be metabolized differently in these patients.

Side Effects:

Common side effects:

- **Drowsiness**, dizziness, or fatigue.
- **Weakness** or muscle fatigue.
- **Nausea** or upset stomach.
- **Headache** or **lightheadedness**.
- **Sleep disturbances** (e.g., insomnia).

Serious but rare side effects:

- **Severe CNS depression:** Excessive drowsiness, confusion, or respiratory depression.
- **Seizures** or **hallucinations** (particularly if Baclofen is stopped suddenly).
- **Hypotension:** Low blood pressure, dizziness, or fainting.
- **Gastrointestinal issues:** Abdominal pain, constipation, or diarrhea.
- **Skin reactions:** Rash, itching, or swelling.

If you experience **serious side effects**, such as **severe dizziness, seizures**, or difficulty breathing, seek immediate medical attention.

Drug Interactions:

- **CNS Depressants:** Baclofen may enhance the sedative effects of other **CNS depressants** like **alcohol, benzodiazepines, opioids**, and **antidepressants**, leading to **increased drowsiness** or respiratory depression.

- **Lithium:** Baclofen may increase the risk of **lithium toxicity**, so if both medications are taken together, regular monitoring of **lithium levels** is recommended.
- **Diuretics:** Baclofen and diuretics may increase the risk of **electrolyte imbalances**, which can affect Baclofen's effectiveness and safety.
- **Antacids:** **Antacids** containing **aluminum** or **magnesium** may decrease Baclofen's absorption, so it is recommended to take Baclofen at least **2 hours** apart from antacids.

Storage:

- Store Baclofen 10 mg tablets at **room temperature** (15°C to 30°C / 59°F to 86°F).
- Keep the tablets in a **tightly closed container**, protected from moisture and light.
- Keep out of the reach of children.

Patient Counseling Information:

- **Take as prescribed:** Be sure to follow your healthcare provider's dosing instructions for optimal results and safety.
- **Avoid abrupt discontinuation:** Never stop Baclofen suddenly. If you need to stop, your doctor will guide you on how to **gradually reduce the dose** to avoid withdrawal symptoms.
- **Monitor side effects:** Report any new or unusual symptoms, such as **extreme drowsiness, muscle weakness, or severe dizziness**, to your healthcare provider immediately.

This information for **Baclofen (10 mg) tablet** outlines its uses, side effects, and important safety information. Always consult your healthcare provider for personalized advice and instructions.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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