Information For the User Baclofen (20mg) Bacloable 20 Tablet

Baclofen (20 mg) Tablet: Product Information

Brand Name: Baclofen 20 mg Tablet Generic Name: Baclofen Strength: 20 mg per tablet Dosage Form: Oral Tablet

Indications:

Baclofen 20 mg tablet is a **muscle relaxant** primarily used for the treatment of muscle spasticity and related conditions. It is indicated for:

- 1. Muscle Spasticity:
 - Spasticity resulting from neurological disorders such as multiple sclerosis, spinal cord injuries, spinal diseases, or cerebral palsy.
 - Used to reduce muscle stiffness, improve motor function, and alleviate discomfort due to muscle spasms.
- 2. Spinal Cord Injury:
 - Muscle spasm and pain related to spinal cord injuries.
- 3. Cerebral Palsy:
 - To treat **spasticity** and related symptoms associated with **cerebral palsy**.

Adults:

- Starting Dose: For most adults, the initial dose is typically 5 mg, taken 3 times a day. The dose can be gradually increased.
- Maintenance Dose: The usual maintenance dose ranges from 20 mg to 80 mg per day, divided into 2-4 doses throughout the day.
- Maximum Dose: The maximum recommended daily dose is generally 80 mg/day in divided doses, but this may vary depending on the patient's response and tolerance.
- **Titration**: Dose adjustments are usually made in increments of **5 mg to 10 mg** every 3-7 days, as tolerated.

Pediatric Use:

 Baclofen may be prescribed for children with spasticity. The dose is generally adjusted based on body weight and age, starting at around 0.3 mg/kg/day, divided into smaller doses.

Administration:

- Take Baclofen 20 mg tablet with or without food.
- Swallow the tablet **whole** with a glass of water.
- It is important to follow the prescribed dosing schedule and not to abruptly stop taking the medication without consulting a healthcare provider.

Mechanism of Action:

Baclofen is a **GABA-B receptor agonist** that acts centrally in the **spinal cord** and the **central nervous system(CNS)**. It inhibits the release of **excitatory neurotransmitters**, which results in **reduced muscle tone** and **spasticity**. Baclofen produces muscle relaxation and reduces spasms without causing significant sedative effects when used at therapeutic doses.

Contraindications:

Baclofen is contraindicated in patients who have:

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

Dosage and Administration:

Warnings and Precautions:

- **CNS Depression**: Baclofen may cause **drowsiness**, **dizziness**, or **sedation**. Use caution when performing tasks that require full alertness, such as driving or operating heavy machinery.
- Withdrawal Symptoms: Discontinuing Baclofen abruptly or reducing the dose too quickly may lead to withdrawal symptoms, such as seizures, hallucinations, agitation, and increased spasticity. Gradual tapering is recommended when discontinuing Baclofen.
- **Renal Impairment**: Use Baclofen with caution in patients with **renal insufficiency** or those undergoing **dialysis** due to decreased clearance of the drug.
- **Hypotension**: Baclofen may lower **blood pressure**, particularly in elderly patients or those receiving antihypertensive medications.

Side Effects:

Common side effects:

- Drowsiness, dizziness, or fatigue.
- Weakness or muscle fatigue.
- Nausea or upset stomach.
- Headache.

Serious but rare side effects:

- Severe CNS depression: Excessive drowsiness, confusion, or respiratory depression.
- Seizures or hallucinations (especially upon abrupt discontinuation).
- **Gastrointestinal symptoms**: Abdominal discomfort, constipation, or diarrhea.
- Skin reactions: Rash, hives, or itching (signs of an allergic reaction).

If any serious side effects occur, such as seizures, difficulty breathing, or chest pain, seek immediate medical attention.

Drug Interactions:

- CNS Depressants: Baclofen may enhance the effects of other CNS depressants (e.g., alcohol, benzodiazepines, sedatives, opioids), leading to excessive sedation or respiratory depression. Caution is advised when used together.
- Antihypertensive Medications: Baclofen can lower blood pressure, and when taken with other antihypertensive drugs, the blood pressure-lowering

effect may be enhanced, increasing the risk of hypotension.

- **Diuretics**: Diuretics may cause **electrolyte imbalances** that can affect Baclofen's effectiveness and safety.
- Lithium: Baclofen may increase the risk of lithium toxicity. Close monitoring of lithium levels is advised if both drugs are used together.
- Antacids: Antacids containing magnesium or aluminum may decrease Baclofen absorption. It is recommended to separate Baclofen and antacid doses by 2 hours.

Storage:

- Store Baclofen 20 mg tablets at room temperature (15°C to 30°C / 59°F to 86°F).
- Keep the tablets in a **tightly closed container**, away from light, moisture, and excessive heat.
- Keep out of reach of children.

Patient Counseling Information:

- Take as prescribed: Ensure that you follow your healthcare provider's instructions regarding the correct dosage and frequency of Baclofen.
- Gradual dose reduction: If you need to stop taking Baclofen, consult your healthcare provider for a tapering schedule to avoid withdrawal symptoms.
- Monitor side effects: If you experience severe side effects like seizures, confusion, or persistent weakness, seek immediate medical attention.

This overview for **Baclofen (20 mg) tablet** provides essential information on its use, dosage, safety precautions, and potential side effects. Always consult your healthcare provider before starting or adjusting any medication.

Manufactured in India for:



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