Safety Data Sheet

Product Name: Baclofen Tablets, USP
Strength: 10 mg and 20 mg

Emergency overview: Each Baclofen tablet intended for oral administration contains Baclofen and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

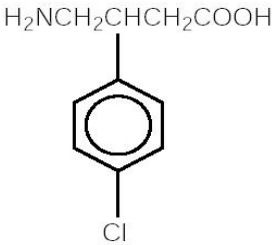
Section 1. Identification

Identification of the product

Product name: Baclofen Tablets, USP

Formula: $C_{10}H_{12}ClNO_2$

Chemical name: 4-amino-3-(4-chlorophenyl)- butanoic acid



Manufacturer/Supplier Identification:

Company: Recipharm pharma services Private Limited

Address: 34th KM, Tumkur Road, (NH 4) Teppada Begur, Nelamangalataluk, Bengaluru, Karnataka 562123

Contact for information: Head – Quality Assurance

Recommended use /

Therapeutic category: Muscle relaxant and Antispastic

Restriction on use / contraindications: Hypersensitivity to baclofen

Section 2: Hazards(s) Identification:

Dose and Administration: Baclofen tablets, USP is available as;

Conventional tablets – 10 mg and 20 mg

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The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 mg to 80 mg daily).

The following dosage titration schedule is suggested:

5 mg t.i.d. (three times in a day) for 3 days

10 mg t.i.d. for 3 days

15 mg t.i.d. for 3 days

20 mg t.i.d. for 3 days

Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (20 mg q.i.d. (four times in a day)).

Adverse Effects:

The most common is transient drowsiness (10 to 63%). In one controlled study of 175 patients, transient drowsiness was observed in 63% of those receiving baclofen compared to 36% of those in the placebo group. Other common adverse reactions are dizziness (5 to 15%), weakness (5 to 15%) and fatigue (2 to 4%).

Others reported:

Neuropsychiatric: Confusion (1 to 11%), headache (4 to 8%), insomnia (2 to 7%); and, rarely, euphoria, excitement, depression, hallucinations, paresthesia, muscle pain, tinnitus, slurred speech, coordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, miosis, mydriasis, diplopia, dysarthria, epileptic seizure.

Cardiovascular: Hypotension (0 to 9%). Rare instances of dyspnea, palpitation, chest pain, syncope.

Gastrointestinal: Nausea (4 to 12%), constipation (2 to 6%); and rarely, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhea, and positive test for occult blood in stool.

Genitourinary: Urinary frequency (2 to 6%); and rarely, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, hematuria.

Other: Instances of rash, pruritus, ankle edema, excessive perspiration, weight gain, nasal congestion.

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Some of the CNS and genitourinary symptoms may be related to the underlying disease rather than to drug therapy. The following laboratory tests have been found to be abnormal in a few patients receiving baclofen: increased SGOT, elevated alkaline phosphatase, and elevation of blood sugar.

Over Dose Effect:

Signs and Symptoms: Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression and seizures.

Treatment: In the alert patient, empty the stomach promptly by induced emesis followed by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Maintain adequate respiratory exchange, do not use respiratory stimulants.

Pregnancy Comments: There are no studies in pregnant women. Baclofen should be used during pregnancy only if the benefit clearly justifies the potential risk to the fetus.

Pregnancy Category: Category C.

Section 3: Composition /information on ingredients:

Component	**CAS No.**
Active Pharmaceutical Ingredient:	
Baclofen USP	1134-47-0
Excipients:	
Microcrystalline Cellulose	9004-34-6
Mannitol	69-65-8
Pre-gelatinized starch	9005-25-8.
Hypromellose	9004-65-3
Sodium starch glycolate type A	9063-38-1
Colloidal silicon dioxide	112926-00-8
Magnesium stearate	557-04-0

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Section 4: First-aid measures

General:

Inhalation:

If dusts are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

Skin contact:

If skin contact with this product occurs, flush affected area with water. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

Eye contact:

If dust of this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

Ingestion:

If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

Most important symptoms/effects, acute and delayed:

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated., Nausea, Headache, Vomiting, Drowsiness, Confusion., fatigue, Dizziness, Weakness, Ataxia. Hallucinations.

Overdose Treatment:

Indication of any immediate medical attention and special treatment needed:

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No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information:

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(S) involved and take precautions to protect themselves.

Section 5: Fire-fighting measures:

Flash point: Not found

Upper flammable limit: Not found

Auto-ignition temperature: Not found

Lower flammable limit: Not found

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Special hazards arising from the substance or mixture: When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including calcium, carbon, magnesium, silicon, sodium and nitrogen oxides).

Special protective equipment and precautions for firefighters: Self-contained breathing apparatus and full protective clothing must be worn in case of fire for firefighting if necessary.

Specific methods: Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards: No unusual fire or explosion hazards noted.

Section 6. Accidental Release Measures:

Spill Response: keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during

clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Method and materials for containment and cleaning up

Stop flow of material, if this is without risk. Prevent product from entering drains. Following product recovery, flush area with water.

Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Section 7. Handling and storage:

Storage: Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Dispense in a well closed container, with a child resistant closure (as required).

Precautions for safe handling: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn. Open containers slowly on a stable surface in areas that have been designated for use of this material. Minimize all exposures to this product. Avoid generation of dusts. Areas in which this product is used should be wiped down, so that these particulates do not accumulate.

Section 8. Exposure controls/personal protection

Respiratory Protection:

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Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Skin Protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices

Eye/Face Protection: Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Protective Clothing: Protective clothing is not normally necessary, however it is good practice to use apron.

Biological limit values: No biological exposure limits noted for the ingredient(s).

Exposure Guidelines: General ventilation normally adequate.

Thermal Hazards: wear appropriate thermal protective clothing, when necessary.

General hygiene considerations: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Engineering controls: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Section 9. Physical and chemical properties

Appearance:

10 mg: White to off-white, round flat faced beveled edged tablets debossed with E 6 on one side and edges engraved diametrically on the other side.

20 mg: White to off-white, round flat faced beveled edged tablets debossed with E 9 on one side and edges engraved diametrically on the other side.

Solubility: This is tablets form hence solubility is not applicable.

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Other information: API of this tablet is white to off-white, crystalline powder is odorless or practically so.

Section 10. Stability and Reactivity:

Conditions to avoid: Exposure to or contact with extreme temperatures, incompatible chemicals

Stable:

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability: Material is stable under normal conditions.

Hazardous reactions: No dangerous reaction known under conditions of normal use.

Decomposition products: None known.

Incompatible materials:. None known.

Section 11. Toxicological Information

General: handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specific formulation.

Target Organ:

Inhalation: Inhalation of dusts generated by damaged tablets of this product may irritate the nose, throat, and lungs. Some information indicates the active ingredient may cause sensitization by inhalation in susceptible individuals. In addition, inhalation may result in adverse effects as described under 'Other Potential Health Effects'.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Some information indicates the active ingredient may cause sensitization by skin contact in susceptible individuals. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

Skin Absorption: No information is available on possible skin absorption.

Ingestion: Ingestion of this product (i.e., through poor hygiene practices) may irritate the mouth, throat, and other tissues of the gastrointestinal system. Repeated ingestion may cause damage to organs and other effects described under 'Other Potential Health Effects'.

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Injection: Not a potential route of exposure for tablets.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common adverse effects have included the most common adverse effects have included transient drowsiness, weakness, fatigue, dizziness. In therapeutic use, adverse effects to the eyes, central nervous, cardiovascular or urinary systems have been reported. Limited evidence of harm to fetus during pregnancy, based on animal data. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known.

Section 12. Ecological Information:

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration:

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information:

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information:

Generic Medicine. Approved by USFDA & the ANDA Number is 211555.

Section 16. Other Information:

None

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Disclaimer: The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.