

Safety Data Sheet

Revision No.: 00

Baclofen Tablets USP, Strength: 10mg/20mg

Pack Size: 100/500/1000 Tablets per bottle

EMERGENCY OVERVIEW

Each Baclofen Tablets, USP intended for oral administration contains Baclofen and excipients generally considered non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

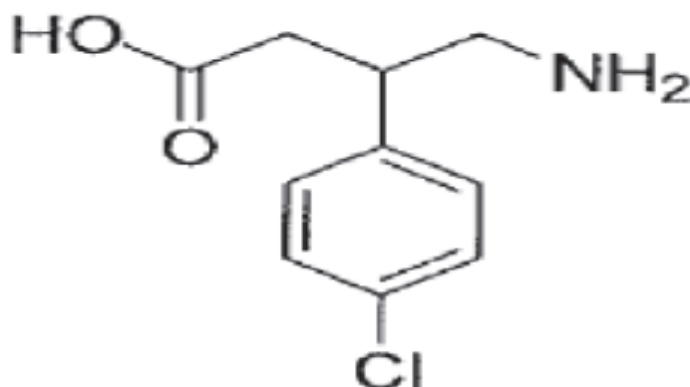
Section 1. IDENTIFICATION

Identification of the product

Product Name: Baclofen Tablets, USP

Formula: C₁₀H₁₂ClNO₂

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



Manufacturer / Supplier identification

Company: Cadila Healthcare Limited Baddi, India

Address: Cadila Healthcare Limited, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.

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Emergency Telephone No. Tel: +91-1795-246841

Recommended use /

Therapeutic Category Useful for alleviation of symptoms of Spasticity associated with multiple sclerosis particularly for the relief of flexor spasms.

Restriction on Use / Hypersensitivity to baclofen.

Contraindications:

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration	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).
Adverse Effects	Transient drowsiness, dizziness, weakness and fatigue.
Over Dose Effect	Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression and seizures.
Contraindications	Hypersensitivity to baclofen.
Pregnancy Comments	Baclofen has been shown to increase the incidence of omphaloceles (ventral hernias) in fetuses of rats given approximately 13 times the maximum dose recommended for human use, at a dose which caused significant reductions in food intake and weight gain in dams. This abnormality was not seen in mice or rabbits.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Baclofen	Not Found	1134-47-0
Inactive Ingredients:		
Microcrystalline Cellulose	Not Found	9004-34-6
Dibasic Calcium Phosphate Anhydrous	Not Found	7757-93-9
Povidone	Not Found	9003-39-8
Pregelatinized Starch	Not Found	9005-25-8
Magnesium Stearate	Not Found	557-04-0
Sodium Starch Glycolate	Not Found	9063-38-1

Section 4. FIRST-AID MEASURES

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Section 5. FIRST FIGHTING MEASURES

Flash Point	Not available
Extinguishing Media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Unusual Fire and Explosion Hazards	No unusual fire or explosion hazards noted.
Fire Fighting Instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

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Section 7. HANDLING AND STORAGE

Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight container.
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
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	Handle in accordance with good industrial hygiene and safety practice.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

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Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Color	White to off-white
Odor	No unpleasant odor.
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Normally stable but formation of toxic gases is possible during heating or in case of fire.
Incompatibility materials to avoid	Strong Oxidizing agents
Polymerization	No
Conditions of Polymerization	Will not occur

Section 11. TOXICOLOGICAL INFORMATION

Inhalation	Due to lack of data, the classification is not possible.
Skin contact	May cause an allergic skin reaction.
Eye contact	Due to lack of data, the classification is not possible.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Not classifiable as to Mutagenic and carcinogenic to humans. In mice, no teratogenic effects were observed, although reductions in mean fetal weight with consequent delays in skeletal ossification were present when dams were given 17 and 34 times the human daily dose. There are no studies in pregnant women.

Section 12. ECOLOGICAL INFORMATION

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

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations	Dispose the waste in accordance with all applicable Federal, State and local laws.
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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, ANDA Number 211659

Section 16. OTHER INFORMATION

Additional Information

NFPA Rating: These ratings are based on NFPA code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material

Health.....3

Fire.....1

Reactivity...0

Date of issue: December 05, 2018

Supersedes edition: New Edition

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.