Safety Data Sheet
FELBAMATE TABLETS, USP
Strength: 400 and 600 mg Pack Size: 30's, 90's 100's and 500's Tablets per bottle and Carton of 100 Tablets (10 x 10 unit Dose)

Revision No.: 00

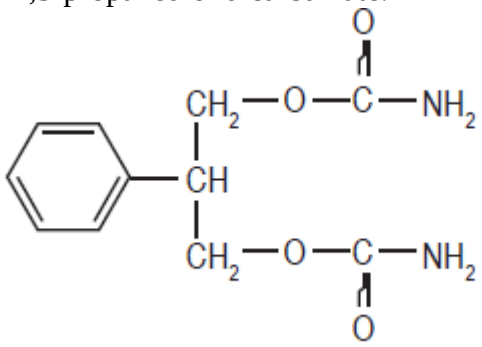
EMERGENCY OVERVIEW
Each Felbamate Tablet, USP intended for oral administration contains Felbamate and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product Name: Felbamate Tablet, USP

Formula: C11H14N2O4
Chemical Name: 2-phenyl-1,3-propanediol dicarbamate.



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd., Matoda, India**

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Recommended use / Therapeutic Category Felbamate tablets, USP are not indicated as a first line antiepileptic treatment (see Warnings). Felbamate tablets, USP are recommended for use only in those patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of aplastic anemia and/or liver failure is deemed acceptable in light of the benefits conferred by its use.

Restriction on Use / Contraindications: Felbamate is contraindicated in patients with known hypersensitivity to felbamate, its ingredients, or known sensitivity to other carbamates. It should not be used in patients with a history of any blood dyscrasia or hepatic dysfunction.

Section 2. Hazard(s) Identification	
Dose and Administration	Felbamate has been studied as monotherapy and adjunctive therapy in adults and as adjunctive therapy in children with seizures associated with Lennox-Gastaut syndrome. As felbamate is added to or substituted for existing AEDs, it is strongly recommended to reduce the dosage of those AEDs in the range of 20 to 33% to minimize side effects
Adverse Effects	The most common adverse reactions seen in association with felbamate in adults during monotherapy are anorexia, vomiting, insomnia, nausea, and headache. The most common adverse reactions seen in association with felbamate in adults during adjunctive therapy are anorexia, vomiting, insomnia, nausea, dizziness, somnolence, and headache. The most common adverse reactions seen in association with felbamate in children during adjunctive therapy are anorexia, vomiting, insomnia, headache, and somnolence
Over Dose Effect	Four subjects inadvertently received felbamate as adjunctive therapy in dosages ranging from 5,400 to 7,200 mg/day for durations between 6 and 51 days. One subject who received 5,400 mg/day as monotherapy for 1 week reported no adverse experiences. Another subject attempted suicide by ingesting 12,000 mg of felbamate in a 12-hour period. The only adverse experiences reported were mild gastric distress and a resting heart rate of 100 bpm. No serious adverse reactions have been reported. General supportive measures should be employed if overdosage occurs. It is not known if felbamate is dialyzable.
Contraindications	Felbamate is contraindicated in patients with known hypersensitivity to felbamate, its ingredients, or known sensitivity to other carbamates. It should not be used in patients with a history of any blood dyscrasia or hepatic dysfunction.
Pregnancy Comments	The incidence of malformations was not increased compared to control in offspring of rats or rabbits given doses up to 13.9 times (rat) and 4.2 times (rabbit) the human daily dose on a mg/kg basis, or 3 times (rat) and less than 2 times (rabbit) the human daily dose on a mg/m2 basis. However, in rats, there was a decrease in pup weight and an increase in pup deaths during lactation. The cause for these deaths is not known. The no effect dose for rat pup mortality was 6.9 times 549 the human dose on a mg/kg basis or 1.5 times the human dose on a mg/m2 basis. Placental transfer of felbamate occurs in rat pups. There are,

Pregnancy Category	however, no studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Felbamate	Not Found	25451-15-4
Inactive Ingredients:		
Lactose Monohydrate	Not Found	64044-51-5
Sodium Starch Glycolate Type A	Not Found	9063-38-1
Povidone K 30	Not Found	9003-39-8
Pregelatinized starch 1500	Not Found	NA
Ferric Oxide (yellow)	Not Found	1309-37-1
FD & C Red no 40Aluminium Lake	Not Found	25956-17-6
D & C yellow no 40Aluminium Lake	Not Found	8004-92-0
Colloidal silicon dioxide	Not Found	7631-86-9
Microcrystalline Cellulose	Not Found	9004-34-6
Magnesium Stearate	Not Found	557-04-0

Section 4. First -aid measures

General

- **After inhalation:**
  Move to fresh air in case of accidental inhalation. assure fresh air breathing.
- **After skin contact:**
  Rinse skin with water/shower
- **After eye contact:**
  Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:**
  Rinse mouth out with water
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed-** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.

Overdose Treatment	Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.

Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted

Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

Section 7. Handling and Storage	
Storage:	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in tight container.

	Precautions for safe handling: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.
Section 8. Exposure controls / personal protection	
Respiratory Protection	Quarter mask (DIN EN 140)
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	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. 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	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.

Section 9. Physical and chemical properties

Appearance	Description of **Felbamate Tablets USP 400 mg**: Off-white to pale yellow colored, capsule shaped biconvex tablets, debossed with "10" and "53" separated by breakline on one side and plain on other side. Description of **Felbamate Tablets USP 600 mg:** Light pink to pink colored, capsule shaped biconvex tablets, debossed with "10" and "54" separated by breakline on one side and plain on other.		
Solubility	Water: < 1 g/l	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
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	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent

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 specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available
Information on toxicological effects	
Acute toxicity	LD50/oral/rat: 315 mg/kg; LD50/oral/mouse: 330 mg/kg LD50/dermal/rat: N/A; LC50/inhalation/rat: N/A.
Further information	Not available
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.
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). In accordance with ADR / RID / IMDG / IATA / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA & the ANDA

Number is 208970
Section 16. Other information
None

Date of issue: 28/06/17 **Supersedes edition:** New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.