

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078939786

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078934167 078934168 078935961 078935963 078935964 078937440 078937543 078939787 078939788 078939789

078939790 078939791

# SAFETY DATA SHEET



ALKEM

**Gabapentin Capsules USP**

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## 1. IDENTIFICATION

<b>Material</b>	<b>Gabapentin Capsules USP 100 mg, 300 mg and 400 mg</b>
<b>Recommended Use</b>	Rx Pharmaceutical for human use
<b>Manufacturer</b>	Alkem Laboratories Ltd. Mumbai - 400013, INDIA.
<b>Distributor</b>	Ascend Laboratories, LLC Parsippany, NJ 07054
<b>Contact Phone Number</b>	<b>001-201-476-1977</b>

## 2. HAZARD(S) IDENTIFICATION

<b>GHS – Classification</b>	Not Classified as hazardous
<b>Label Elements</b>	
<b>Signal Word:</b>	Not classified
<b>Hazard Statements:</b>	Not classified in accordance with international standards for workplace safety
<b>Other Hazards</b>	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
<b>Note</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

<b>Active Ingredient</b>	<b>CAS No.</b>	<b>Quantity</b>	
Gabapentin	60142-96-3	100 mg/Capsules, 300 mg/Capsules, and 400 mg/Capsules	
<b>Inactive Ingredient</b>	<b>CAS No.</b>	<b>Inactive Ingredient</b>	<b>CAS No.</b>
Starch	9005258	Sodium Lauryl Sulfate	151213

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Talc	14807966	Titanium Dioxide	13463677
Lactose	63423	Ferric Oxide Yellow	51274001
Gelatin	9000708	Ferric Oxide Red	1309371

### 4. FIRST-AID MEASURE

<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<b>Symptoms and Effects of Exposure</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
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<b>Medical Conditions</b>	None known
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#### Aggravated by Exposure

#### Indication of the Immediate Medical Attention and Special Treatment Needed

<b>Notes to Physician</b>	None
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### 5. FIRE-FIGHTING MEASURE

<b>Suitable Extinguishing Media</b>	Carbon dioxide, dry chemical or water.
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#### Special Hazards from Arising from the Substance or Mixture

**Hazardous Combustion Products** Formation of toxic gases is possible during heating or fire

<b>Fire/Explosion Hazards</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Advice for Fire-Fighters</b>	During all firefighting activities, wear appropriate protective

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equipment, including self-contained breathing apparatus

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions Protective Equipment and Emergency Procedure</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Method and Material for Containment and Cleaning-up</b>	
<b>Measures for Cleaning/Collecting</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

<b>Precaution for Safe Handling</b>	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage Conditions</b>	Store at 20° to 25°C (68° to 77°F); [see USP Controlled Room Temperature].
<b>Specific End Use</b>	Pharmaceutical drug product

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Appropriate Engineering Controls</b>	General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
<b>Hands</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent).
<b>Respiratory Protection</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent).

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State</b>	Solid
<b>Form</b>	Capsules

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Sr. No.	Strength	Description	Packs	NDC No.
1	100 mg	White to off white crystalline powder filled in size "4" white hard gelatin capsule imprinted "216" on body with blue ink.	Bottles of 100	67877-222-01
			Bottles of 500	67877-222-05
			Bottles of 1000	67877-222-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-222-38
2	300 mg	White to off white crystalline powder filled in size "1" yellow colour hard gelatin capsule imprinted "215" on body with blue ink.	Bottles of 100	67877-223-01
			Bottles of 500	67877-223-05
			Bottles of 1000	67877-223-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-223-38
3	400 mg	White to off white crystalline powder filled in size "0" Orange colour hard gelatin capsule imprinted "214" on body with blue ink.	Bottles of 100	67877-224-01
			Bottles of 500	67877-224-05
			Bottles of 1000	67877-224-10
			One Carton of 100 (10 x 10 Unit-dose capsules)	67877-224-38

### Explosive Properties

Not explosive

### Oxidizing Properties

The substance or mixture is not classified as oxidizing

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available.

### Chemical Stability

Stable at normal conditions of use.

### Possibility of Hazardous Reactions

#### Polymerization

Will not occur

#### Conditions to Avoid

Fine particles (such as dust and mists) may fuel fires/explosions

#### Incompatible Materials

As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

#### Short Term

Dust may cause irritation (based on components). The active ingredient is not acutely toxic.

#### Known Clinical

Adverse effects associated with therapeutic use include dizziness, tiredness,



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**Effects** swelling, and nausea

#### Acute Toxicity (Species, Route, End Point, Dose):

##### Gabapentin

<u>Species</u>	<u>Route</u>	<u>End Point</u>	<u>Dose</u>
Mouse	Oral	LD50	> 5000 mg/kg
Rat	Oral	LD50	> 5000mg/kg
Rat	IV	LD50	> 2000mg/kg
Mouse	IV	LD50	1000-2000mg/kg
Rat	Subcutaneous	LD50	> 4000mg/kg

##### Talc (non-asbestiform)

<u>Species</u>	<u>Route</u>	<u>End Point</u>	<u>Dose</u>
Rat	Oral	LD50	> 1600 mg/kg

#### **Acute Toxicity Comments:**

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization (Study Type, Species, Severity):

##### Gabapentin

<u>Study Type</u>	<u>Species</u>	<u>Severity</u>
Eye Irritation	Rabbit	Non-irritating

#### Repeated Dose Toxicity (Duration, Species, Route, Dose, End Point, Target Organ):

##### Gabapentin

<u>Duration</u>	<u>Species</u>	<u>Route</u>	<u>Dose</u>	<u>End Point</u>	<u>Target Organ</u>
52 weeks	Rat	Oral	250 mg/kg/day	NOAEL	Liver, Kidney
52 weeks	Monkey	Oral	250 mg/kg/day	NOAEL	Not identified
13 weeks	Mouse	Oral	1000 mg/kg/day	NOAEL	No effect at max dose

#### Reproduction & Developmental Toxicity (Study Type, Species, Route, Dose, End Point,

##### Effect(s)):

##### Gabapentin

<u>Study Type</u>	<u>Species</u>	<u>Route</u>	<u>Dose</u>	<u>End Point</u>	<u>Effect(s)</u>
Reproductive & Fertility	Rat	Oral	500 mg/kg/day	NOAEL	Negative
Embryo/Fetal Development	Mouse	Oral	3000 mg/kg/day	NOAEL	No effects at max dose
Embryo/Fetal	Rat	Oral	300	NOAEL	Developmental toxicity,



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Development			mg/kg/day		Not Teratogenic
Peri-/Postnatal	Rat	Oral	500	NOAEL	Negative
Development			mg/kg/day		

#### Genetic Toxicity (Study Type, Cell Type/Organism, Result):

##### Gabapentin

<u>Study Type</u>	<u>Cell Type/Organism,</u>	<u>Result</u>
Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Negative
In Vitro Chromosome Aberration	Hamster Lung Cells	Negative
In Vivo Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
In Vivo Chromosome Aberration	Hamster Bone Marrow	Negative

#### Carcinogenicity (Duration, Species, Route, Dose, End Point, Effect(s)):

##### Gabapentin

<u>Duration</u>	<u>Species</u>	<u>Route</u>	<u>Dose</u>	<u>End Point</u>	<u>Effect(s)</u>
2 Year(s)	Mouse	Oral, in feed	2000 mg/kg/day	NOEL	Not carcinogenic
2 Year(s)	Male Rat	Oral, in feed	1000 mg/kg/day	NOEL	Malignant tumors, Pancreas

## 12. ECOLOGICAL INFORMATION

<b>Environmental Overview</b>	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
<b>Toxicity</b>	No data available
<b>Persistence and Degradability</b>	No data available

#### **Bio-accumulative Potential :**

##### **Gabapentin**

##### **Partition Coefficient:**

<u>Method</u>	<u>pH</u>	<u>Endpoint</u>	<u>Value</u>
Predicted	7.4	Log D	-1.31

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATION

<b>Waste Treatment Methods:</b>	Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the
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relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is 090858.

#### **Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

##### **Gabapentin**

Standard for the Uniform Scheduling for drugs and poisons	Schedule 4
EU EINECS/ELINCS List	262-076-3

##### **Starch**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register	Present
EU EINECS/ELINCS List	232-679-6

##### **Lactose**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS)	Present
REACH - Annex IV - Exemptions from the obligations of Register	Present
EU EINECS/ELINCS List	200-559-2

##### **Talc**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS)	Present
EU EINECS/ELINCS List	238-877-9

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## 16. OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections, which pertain to their particular conditions.

**Alkem or Ascend** shall not be held liable for any damage resulting from handling or from contact with the above product. Alkem or Ascend reserves the right to revise this SDS.

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

Date of Preparation: 26/11/2019