

SAFETY DATA SHEETS

This SDS packet was issued with item:

078948831

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

078948822 078948824 078948829 078948832 078948833

Material Safety Data Sheet

Gabapentin Tablet

Strength: ~~600/300~~ mg. Pack Size: 100/500/~~1000~~ Capsules 100/300/400 Tablets per bottle (for ~~600~~ mg) Revision No.: 00
100/300/400 100/500/~~1000~~ and unit dose blister cartons of 100(10X10) unit dose Tablet/bottle(for 800mg)

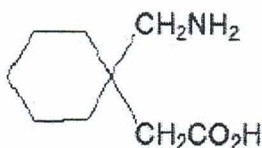
EMERGENCY OVERVIEW

Gabapentin Tablets contain Gabapentin and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name: Gabapentin Tablet
Formula: $C_9H_{17}NO_2$
Chemical Name: 1-(aminomethyl)cyclohexanecarboxylic acid
Therapeutic Category: Antiepileptic



Gabapentin

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India
Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No. Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Gabapentin	Not Found	60142-96-3
Inactive ingredients :		
Copovidone	Not Found	9003-39-8
Low substituted hydroxypropyl cellulose	Not Found	9004-64-2
Magnesium stearate	Not Found	577-04-0
Mannitol	Not Found	69-65-8
Poloxamer	Not Found	106392-12-5
Talc	Not Found	14807-96-6

Material Safety Data Sheet

Gabapentin Tablet

Strength: ~~600/800~~ mg.

Pack Size: 100/500/1000 ~~Tablets~~ per bottle (for ~~600~~ mg)

Revision No.: 00

100/300/400

100/500/1000 and unit dose blister cartons of 100(10X10) unit dose Tablet/bottle(for 800mg)

Povidone

Not Found

9003-39-8

Section 3. Health Hazards Information

Dose and Administration

~~Tablets~~ **Capsules** are given orally with or without food. Patients should be informed that, should they break the scored 600 or 800 mg tablet in order to administer a half-tablet, they should take the unused half-tablet as the next dose. Half-tablets not used within several days of breaking the scored tablet should be discarded.

~~Tablets~~ **Capsules** If gabapentin ~~tablets~~ dose is reduced, discontinued or substituted with an alternative medication, this should be done gradually over a minimum of 1 week (a longer period may be needed at the discretion of the prescriber).

Adverse Effects

Postherpetic Neuralgia:

~~Tablets~~ **Capsules**

The most commonly observed adverse events associated with the use of gabapentin ~~tablets~~ in adults, not seen at an equivalent frequency among placebo-treated patients, were dizziness, somnolence, and peripheral edema.

Epilepsy:

~~Tablets~~ **Capsules**

The most commonly observed adverse events associated with the use of gabapentin ~~tablets~~ in combination with other antiepileptic drugs in patients >12 years of age, not seen at an equivalent frequency among placebo-treated patients, were somnolence, dizziness, ataxia, fatigue, and nystagmus. The most commonly observed adverse events reported with the use of gabapentin tablets in combination with other antiepileptic drugs in pediatric patients 3 to 12 years of age, not seen at an equal frequency among placebo-treated patients, were viral infection, fever, nausea and/or vomiting, somnolence, and hostility

Adverse events following the abrupt discontinuation of gabapentin have also been reported. The most frequently reported events were anxiety, insomnia, nausea, pain and sweating.

Over Dose Effect

~~Tablets~~ **Capsules** Acute oral overdoses of gabapentin ~~tablets~~ up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea were observed. All patients recovered with supportive care.

Medical Conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

~~Tablets~~ **Capsules** Taking gabapentin ~~tablets~~ with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

Contraindications

~~Tablets~~ **Capsules** Gabapentin ~~tablets~~ are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

Material Safety Data Sheet
Gabapentin Tablet

Strength: ~~600/800~~ mg.

Pack Size: 100/500/~~1000~~ ~~Tablets~~ per bottle (for ~~600~~ mg)

Revision No.: 00

100/300/400

100/500/~~1000~~ and unit dose blister cartons of 100(10X10) unit dose Tablet/bottle(for 800mg)

Capsules 100/300/400

Pregnancy Comments There are no adequate and well- controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category C

Section 4. First aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Contact with eyes

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment

Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

Section 5. Fire – fighting measures

Flash point

Not Found

Upper Flammable Limit:

Not Found

Auto-Ignition Temperature:

Not Found

Lower Flammable Limit:

Not Found

Extinguishing Media

Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Fire and Explosion Hazard

This material is assumed to be combustible.
As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

Fire Fighting Procedure

As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Material Safety Data Sheet

Gabapentin Tablet

Strength: ~~600/300~~ mg.

100/300/400

Pack Size: 100/500/1000 ~~Tablets~~ per bottle (for ~~600~~ mg)

Capsules 100/300/400

Revision No.: 00

100/500/1000 and unit dose blister cartons of 100(10X10) unit dose Tablet/bottle(for 800mg)

Section 6. Accidental Release Measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage

Store at 20° to 25° C (68° to 77° F). Dispense in a tight container.

Section 8. Exposure controls and personal protection

Respiratory Protection

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing

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

Section 9. Physical and chemical properties

Appearance

~~Gabapentin Tablets, 600mg~~ Capsules 100/300/400 are white to off-white, oval-shaped, biconvex, film-coated tablets debossed with 'ZE72' with bisect on one side and plain with bisect on other side

~~Gabapentin Tablets, 800mg~~ Capsules 100/300/400 are white to off-white, oval-shaped, bevelled-edge, biconvex, film-coated ~~tablets~~ debossed with 'ZE71' with bisect on one side and plain with bisect on other side

Solubility in water

Freely soluble

Odour

Odourless

Boiling point

No Data Available

Melting Point

No Data Available

Evaporation rate

No Data Available

Vapour density

No Data Available

Reactivity in water

No Data Available

Evaporation rate

No Data Available

Percentage Volatile by volume

No Data Available

Specific gravity

No Data Available

Vapour pressure

No Data Available

Other information

Not Applicable

Section 10. Stability and Reactivity

Material Safety Data Sheet
Gabapentin Tablet

Capsules

100/300/400

Strength: ~~600/300~~ mg.

Pack Size: 100/500/~~1000~~ Tablets per bottle (for ~~600~~ mg)

Revision No.: 00

100/300/400

100/500/~~1000~~ and unit dose blister cartons of 100(10X10) unit dose Tablet/bottle(for 800mg)

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

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.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	Not Applicable

Section 12. Ecological information

No data available on Ecotoxicity

Section 13. Disposal Consideration

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

Section 14. Transport Information

May be shipped normally as a non hazardous material.

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 40663

Section 16. Other information

None

Date of issue: 13/07/2012

Supersedes edition of: New Edition

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