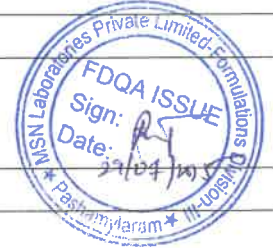
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Product Name	Pregabalin Capsules 25/50/75/100/150/200/225/300 mg	

1. Product Information

Product Name: Pregabalin Capsules 25/50/75/100/150/200/225/300 mg



2. Composition/Information on Ingredients

C.A.S. No : : 148553-50-8
 Molecular Formula : $C_8H_{17}NO_2$
 Molecular Weight : 159.23
 Chemical Name : (S)-3-(aminomethyl)-5-methylhexanoic acid .

3. Hazards Identification

Statement of Hazard: WARNING

Additional Hazard Information: Suspected of damaging the unborn child.

Long Term:

Known Clinical Effects: Animal studies indicate that this material may cause adverse effects on the fetus.

Adverse effects most commonly reported in clinical use include dizziness, blurred vision, weight gain, sleepiness (somnia), inability to concentrate, swelling, dry mouth.

Hypersensitivity reactions may also occur in susceptible individuals. Other less common effects include suicidal behavior.

EU Indication of danger: Harmful

Toxic to Reproduction: Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the

unborn child.

Australian Hazard Classification Hazardous Substance. Non-Dangerous Goods.

(NOHSC):


4. First Aid Measures

Eye Contact: Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

Skin Contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

Ingestion: If swallowed, wash out mouth with copious amounts of water; call a physician.

Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

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5. Emergency Overview

Major Health Hazards: No major health hazards are known.

6. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

7. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: 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.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.


Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

8. Handling and Storage

General Handling: 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 hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

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9. Exposure Controls/Personal Protection

Refer to available public information for specific member state Occupational Exposure Limits.

Pregabalin	
OEL TWA-8 Hr:	500µg/m ³
Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³ 2
Belgium OEL - TWA	mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
Czech Republic OEL - TWA	3.0 mg/m ³
	2.0 mg/m ³
Denmark OEL - TWA	10 mg/m ³
Finland OEL - TWA	0.3 fiber/cm ³
Greece OEL - TWA	0.5 fiber/cm ³
	5 mg/m ³
Hungary OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	2 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	10 mg/m ³
	0.8 mg/m ³
Netherlands OEL -TWA	2 mg/m ³
OSHA - Final PELs - Table Z-3	1 mg/m ³
Mineral D:	20mg/m ³
Poland OEL - TWA	20 mppcf
	4.0 mg/m ³
Portugal OEL - TWA	1.0 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	2 mg/m ³
Slovenia OEL TWA	10 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	2 mg/m ³
	1 mg.m ³

10. Physical and Chemical Properties

Appearance:


25 mg: White to off white color granular powder filled in Size“4” hard gelatin capsules having White Opaque color body imprinted “PGBN” and Light Blue Opaque cap imprinted “25” with black ink.

50 mg: White to off white color granular powder filled in Size“4” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “50” with black ink.

75 mg : White to off white color granular powder filled in Size“4” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “75” with black ink.

100 mg : White to off white color granular powder filled in Size“3” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “100” with black ink.

150 mg : White to off white color granular powder filled in Size“2” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “150” with black ink.

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200 mg : White to off white color granular powder filled in Size“1” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “200” with black ink.
 225 mg : White to off white color granular powder filled in Size“1” hard gelatin capsules having White Opaque body imprinted “PGBN” and Light Blue Opaque cap imprinted “225” with black ink.
 300 mg : White to off white color granular powder filled in Size“0” hard gelatin capsules having White Opaque body imprinted “ PGBN” and Light Blue Opaque cap imprinted “300” with black ink.

11. Stability and Reactivity

Stability: Stable under normal conditions of use.


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

Hazardous Decomposition Products: None known

12. Toxicological Information

- **General Information:** The information included in this section describes the potential hazards of the individual ingredients.
- **Acute Toxicity: (Species, Route, End Point, Dose)**
- **Talc (non-asbestiform)**
- Rat Oral LD50 > 1600 mg/kg
- **Pregabalin**
- Rat IV LD50 > 300 mg/kg
- Mouse Oral LD50 > 5000 mg/kg
- Rat Oral LD50 > 5000 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)**
- **Pregabalin**
- Skin Sensitization - LLNA Rat Negative
- Skin Sensitization - Beuhler Guinea Pig Negative
- **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

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- **Pregabalin**
- 13 Week(s) Rat Oral 50 mg/kg/day NOEL Central nervous system, Male reproductive system
- 4 Week(s) Rat Oral 500 mg/kg/day LOEL Central Nervous System, Male reproductive system
- 4 Week(s) Monkey Oral 100 mg/kg/day NOEL Central Nervous System
- 52 Week(s) Rat Oral 50 mg/kg/day LOEL Blood forming organs

• **Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

- **Pregabalin**
- Peri-/Postnatal Development Rat Oral 100 mg/kg/day NOEL Developmental toxicity, Fertility
- Fertility & Early Embryonic Development - Males Rat Oral 250 mg/kg/day NOEL No effects at maximum dose
- Fertility & Embryonic Development-Females Rat Oral 1250 mg/kg/day NOEL Negative
- Embryo / Fetal Development Rat Oral 500 mg/kg/day NOEL Not Teratogenic
- Embryo / Fetal Development Rabbit Oral 500 mg/kg/day NOEL Not Teratogenic

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

- **Pregabalin**
- Bacterial Mutagenicity (Ames) Bacteria Negative
- *In Vivo* Unscheduled DNA Synthesis Rat Negative
- *In Vivo* Micronucleus Mouse Negative
- *In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative


13. Ecological Information

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Pregabalin
Daphnia magna (Water Flea) EC50 48 Hours > 1000 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 1000 mg/L
 Green algae OECD EbC50 72 Hours > 300 mg/L Green
 Algae OECD ErC50 72 Hours > 300 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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Aspergillus niger (Fungus) OECD MIC > 1000 mg/L
Trichoderma viride (Fungus) OECD MIC > 1000 mg/L
Clostridium perfringens (Bacterium) OECD MIC > 997 mg/L
Bacillus subtilis (Bacterium) OECD MIC >1000 mg/L
Nostoc sp. (Freshwater Cyanobacteria) OECD MIC > 1000 mg/L

14. Disposal Considerations

Dispose of in accordance with prevailing country, federal, state and local regulations.

15. Transport Information

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

16. Regulatory Information

EU Symbol:	Xn
EU Indication of danger:	Harmful Toxic to Reproduction: Category 3

EU Risk Phrases:	R63 - Possible risk of harm to the unborn child.
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EU Safety Phrases:	S22 - Do not breathe dust. S36/37 - Wear suitable protective clothing and gloves.
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OSHA Label:
WA
RNI
NG
Suspected of damaging the unborn child.


Canada - WHMIS:
Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Pregabalin
U.S. Drug Enforcement Administration:
Standard for the Uniform Scheduling
for Drugs and Poisons:

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

Talc (non-asbestiform)

Corn Starch

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Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Schedule V Controlled Substance Schedule 4
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Lactose NF, monohydrate Australia (AICS):	Present Present 238-877-9
	Present Present Present 232-679-6
	Present

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V

17. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.