LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	**Armodafinil Tablets, C-IV** **50 mg, 150 mg, 200 mg and 250 mg**
Manufacturer	**Lupin Limited** Goa 403 722 INDIA
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Health	Armodafinil tablets are contraindicated in patients with known hypersensitivity to modafinil or armodafinil or its inactive ingredients.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition / Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Armodafinil	68693-11-8

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Seek Medical attention.

Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	There were no overdoses reported in the armodafinil clinical studies. Symptoms of armodafinil overdose are likely to be similar to those of modafinil. Symptoms of overdose in modafinil clinical trials included excitation or agitation, insomnia, and slight or moderate elevations in hemodynamic parameters. From post-marketing experience with modafinil, there have been reports of fatal overdoses involving modafinil alone or in combination with other drugs. Symptoms most often accompanying modafinil overdose, alone or in combination with other drugs have included insomnia; central nervous system symptoms such as restlessness, disorientation, confusion, excitation and hallucination; digestive changes such as nausea and diarrhea; and cardiovascular changes such as tachycardia, bradycardia, hypertension and chest pain. No specific antidote exists for the toxic effects of a armodafinil overdose. Such overdoses should be managed with primarily supportive care, including cardiovascular monitoring.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Toxic gases may be emitted from fires involving this product, therefore self-contained breathing apparatus and full protective equipment are recommended for fire fighters.
Extinguishing Media	No restriction.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	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.

Section 7: Handling and Storage

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Handling	If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment. 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.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	Armodafinil Tablets are available as follows: 50 mg: White to off white, round, biconvex tablets debossed with "LU" on one side "X41" on the other side. NDC 68180-569-07 - Bottles of 60 150 mg: White to off white, oval, biconvex tablets debossed with "LU" on one side "X43" on the other side.

NDC 68180-571-07 - Bottles of 60
NDC 68180-571-02 - Bottles of 500

200 mg: White to off white, oval, biconvex tablets debossed with "LU" on one side "X44" on the other side.
NDC 68180-572-07 - Bottles of 60
NDC 68180-572-02 - Bottles of 500

250 mg: White to off white, oval, biconvex tablets debossed with "C04" on one side "LL" on the other side.
NDC 68180-573-07 - Bottles of 60
NDC 68180-573-02 - Bottles of 500

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
In a mouse carcinogenicity study, armodafinil (R-modafinil) was administered at oral doses of up to 300 mg/kg/day in males and 100 mg/kg/day in females for approximately two years, no tumorigenic effects were observed.
In a rat carcinogenicity study modafinil (a mixture of R- and S-modafinil) was administered at oral doses of up to 60 mg/kg/day for two years; no tumorigenic effects were observed.
At the highest doses studied in mouse and rat, the plasma armodafinil exposures (AUC) were less than that in humans at the MRHD of armodafinil (250 mg/day).

Mutagenesis
Armodafinil was negative in an in vitro bacterial reverse mutation assay and in an in vitro chromosomal aberration assay in human lymphocytes.
Modafinil was negative in a series of in vitro (i.e., bacterial reverse mutation, mouse lymphoma tk, chromosomal aberration in human lymphocytes, cell transformation in BALB/3T3 mouse embryo cells) or in vivo (mouse bone marrow micronucleus) assays.

Impairment of Fertility
A fertility and early embryonic development (to implantation) study was not conducted with armodafinil alone.
Oral administration of modafinil (doses of up to 480 mg/kg/day) to male and female rats prior to and throughout mating, and continuing in females through day 7 of gestation produced an increase in the time to mate at the highest dose; no effects were observed on other fertility or reproductive parameters. The no-effect dose of 240 mg/kg/day was associated with a plasma armodafinil AUC less than that in humans at the MRHD of armodafinil.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16: Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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