Safety Data Sheet
MODAFINIL TABLETS USP.
Strength: 100 mg and 200 mg.
Pack Size: 30's, 90's 100's, Tablets per bottle.

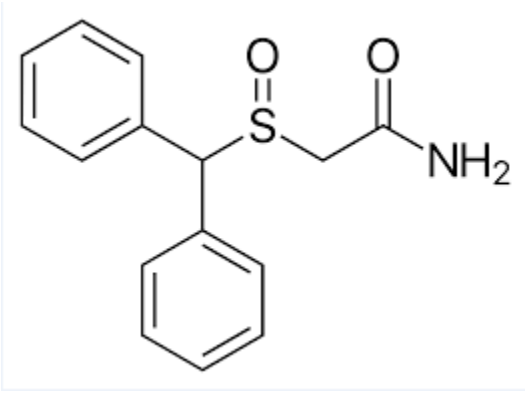
Revision No.: 00

EMERGENCY OVERVIEW
Each Modafinil Tablets USP intended for oral administration contains Modafinil Tablets USP 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:	**MODAFINIL TABLETS USP**
Formula:	C15H15NO2S
Chemical Name:	The chemical name for modafinil is 2-[(diphenylmethyl)sulfinyl]acetamide.



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd., Matoda, India**
Address:	Cadila Healthcare Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
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Recommended use / Therapeutic Category	Modafinil tablets are indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD). Limitations of Use In OSA, modafinil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with modafinil for excessive sleepiness.
Restriction on Use / Contraindications:	Modafinil is contraindicated in patients with known hypersensitivity to Modafinil or armodafinil

Section 2. Hazard(s) Identification	
Dose and Administration	Dosage in Narcolepsy and Obstructive Sleep Apnea (OSA) The recommended dosage of modafinil for patients with narcolepsy or OSA is 200 mg taken orally once a day as a single dose in the morning. Doses up to 400 mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200 mg/day dose Dosage in Shift Work Disorder (SWD) The recommended dosage of modafinil for patients with SWD is 200 mg taken orally once a day as a single dose approximately 1-hour prior to the start of their work shift. Dosage Modifications in Patients with Severe Hepatic Impairment In patients with severe hepatic impairment, the dosage of modafinil should be reduced to one-half of that recommended

	for patients with normal hepatic function Use in Geriatric Patients Consideration should be given to the use of lower doses and close monitoring in geriatric patients
Adverse Effects	The following serious adverse reactions are described elsewhere in the labeling: • Serious Rash, including Stevens-Johnson Syndrome • Angioedema and Anaphylaxis Reactions • Multi-organ Hypersensitivity Reactions • Persistent Sleepiness • Psychiatric Symptoms • Effects on Ability to Drive and Use Machinery • Cardiovascular Events
Over Dose Effect	If you take more than your prescribed dose or if you take an overdose of modafinil tablets, call your doctor or go to the nearest hospital emergency room right away. Symptoms of an overdose of modafinil tablets may include · trouble sleeping · restlessness · confusion · feeling disoriented · feeling excited · hearing, seeing, feeling, or sensing things that are not really there (hallucinations) · nausea and diarrhea · a fast or slow heartbeat · chest pain · increased blood pressure
Contraindications	Modafinil is contraindicated in patients with known hypersensitivity to modafinil or armodafinil or its inactive ingredients
Pregnancy Comments	There are no adequate and well-controlled studies of modafinil in pregnant women. Intrauterine growth restriction and spontaneous abortion have been reported in association with modafinil (a mixture of R-and S-modafinil) and armodafinil (the R-enantiomer of modafinil). Although the pharmacology

of modafinil is not identical to that of the sympathomimetic amines, it does share some pharmacologic properties with this class. Certain of these drugs have been associated with intrauterine growth restriction and spontaneous abortions. Whether the cases reported with modafinil are drug-related is unknown. In studies of modafinil and armodafinil conducted in rats (modafinil, armodafinil) and rabbits (modafinil), developmental toxicity was observed at clinically relevant plasma exposures. Modafinil should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Modafinil (50 mg/kg/day, 100 mg/kg/day, or 200 mg/kg/day) administered orally to pregnant rats throughout organogenesis caused, in the absence of maternal toxicity, an increase in resorptions and an increased incidence of visceral and skeletal variations in the offspring at the highest dose tested. The higher no-effect dose for embryofetal developmental toxicity in rats (100 mg/kg/day) was associated with a plasma modafinil AUC less than that in humans at the recommended human dose (RHD) of modafinil (200 mg/day). However, in a subsequent study of up to 480 mg/kg/day of modafinil, no adverse effects on embryofetal development were observed. Oral administration of armodafinil (60 mg/kg/day, 200 mg/kg/day, or 600 mg/kg/day) to pregnant rats throughout organogenesis resulted in increased incidences of fetal visceral and skeletal variations and decreased fetal body weight at the highest dose tested. The highest no-effect dose for embryofetal developmental toxicity in rats (200 mg/kg/day) was associated with a plasma armodafinil AUC less than that in humans at the RHD of modafinil.

Modafinil administered orally to pregnant rabbits throughout organogenesis at doses of up to 100 mg/kg/day had no effect on embryofetal development; however, the doses used were too low to adequately assess the effects of modafinil on embryofetal development. In a subsequent developmental toxicity study evaluating doses of 45 mg/kg/day, 90 mg/kg/day, and 180 mg/kg/day in pregnant rabbits, the incidences of fetal structural alterations and embryofetal death were increased at the highest dose. The highest no-effect dose for developmental toxicity (100 mg/kg/day) was associated with a plasma modafinil AUC similar to that in humans at the RHD of modafinil.

	Modafinil administration to rats throughout gestation and lactation at oral doses of up to 200 mg/kg/day resulted in decreased viability in the offspring at doses greater than 20 mg/kg/day, a dose resulting in a plasma modafinil AUC less than that in humans at the RHD of modafinil. No effects on postnatal developmental and neurobehavioral parameters were observed in surviving offspring
Pregnancy Category	C

Section 3. Composition / information on ingredients		
Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Modafinil Tablets	Not Found	68693-11-8
Inactive Ingredients:		
Lactose Monohydrate (Pharmatose 200 M, DMV)	Not Found	Not Found
Microcrystalline Cellulose 102 (Comprecel M102D+), Mingtai	Not Found	Not Found
Croscarmellose Sodium (Acdisol)	Not Found	74811-65-7
Povidone (K-90) (Kollidon 90 F BASF)	Not Found	9003-39-08
Magnesium Stearate (DR, Paul Lohmann)	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, 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	No additional information available
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) Dispense in a tightly closed container with a child-resistant closure (as required). Keep out of the reach of children. **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 **Modafinil Tablets USP 100 mg** is White to off white capsule shaped uncoated tablets debossed with' 1072' on one side and plain on other side. Description of **Modafinil Tablets USP 200 mg** is White to off white capsule shaped uncoated scored tablets debossed with'10 & 73' on either side of score line on one side and plain on other side

Solubility	Not available.	**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	No drug or dose related occurrence of carcinogenesis was evident in rats receiving oral doses up to 7.3 times the maximum recommended human dose of 400mg/day on mg/m2 basis
Further information	NA

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	
	Not Available
Section 16. Other information	
	None

Date of issue: 27/04/20 **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.