SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY

a)	**Product Name**	:	Ondansetron Injection USP, 2 mg/mL
b)	**Common/Trade Name**	:	Ondansetron Injection USP, 2 mg/mL
	Chemical Names	:	1,2,9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one,monohydrochliride
	Chemical Family	:	Serotonin-blocking drug
c)	**Product Use**	:	Pharmaceutical, Injectable
	Product Type	:	Regulated Prescription Drug
	Container Information	:	2mL Vial
d)	**Manufacturers Name & Address**	:	**Gland Pharma Limited**
		:	Survey No.: 143–148, 150&151
		:	Near Gandimaisamma Cross Roads,
		:	D.P.Pally, Quthubullapur Mandal
		:	Ranga Reddy District
		:	Hyderabad- 500043
		:	Telangana, India
e)	**Telephone Number for Info**	:	+91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATION

1. **Classification**

NFPA Rating

Health Hazard	:	NA
Fire Hazard	:	NA
Reactivity Hazard	:	NA

2. **Unknown Acute Toxicity:** **N/A**

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

a) Chemical Name	b) Common Name/Synonym	%Composition or other measure	c) CAS Number	d) Impurities / Stabilizing Additives
1,2,9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1yl)methyl]-4H-carbazol-4-one,monohydrochliride	Ondansetron Hydrochloride Dihyrated	2.5 mg/mL	103639-04-9	N/A
Sea salt	Sodium Chloride	9.0 mg/mL	7647-14-5	N/A
2-Hydroxy-1,2,3-propanetricarboxylic acid monohydrate	Citric acid monohydrate	0.5 mg/mL	5949-29-1	N/A
dihydrate	Sodium citrate dihydrate	0.25 mg/mL	6132-04-3	N/A
Water	Water for Injection	QS to 1 mL	7732-18-5	N/A

SECTION 4 – FIRST AID MEASURES

Eye Exposure : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Exposure : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Injection : Under normal use with supervision of a physician, Palonosetron hydrochloride injection

I**nhalation** : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Notes to Physician : See patient package insert in shipping carton for complete information

SECTION 5 – FIRE FIGHTING MEASURES

a) Extinguishing Media : As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

b) Special Protective Equipment / Precautions : No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Spill : Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Prevent entry into sewers and surface drainage systems. Dispose of spill materials according to the applicable federal, state, or local regulations.

SECTION 7 – HANDLING AND STORAGE

General Handling : No special handling is required for hazard control under conditions of normal product use.

Storage Conditions : No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

SECTION 8 – EXPOSURE CONTROLS/ PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Ondansetron Hydrochloride	OSHA ACGIH AIHA	PEL TLV WEEL	8-hr TWA: Not Established

b) Engineering Controls

Ventilation : Engineering controls are normally not needed during the intended use of this product.

c) Individual Protection Measures

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Respiratory Protection	:	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Eye Protection	:	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin Protection	:	If skin contact with the product solution is likely, the use of latex or nitrile gloves is recommended.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	**Appearance/Description**	:	A clear, colorless solution shall be free from all visible particles and extraneous matter.
b)	**Odor**	:	Not available
c)	**Odor Threshold**	:	None
d)	**P^H**	:	3.3 to 4.0
e)	**Melting Point**	:	Not available
f)	**Initial Boiling Point**	:	Not available
g)	**Flash Point**	:	Not available
h)	**Evaporation Rate**	:	Not available
i)	**Flammability**	:	Not available
j)	**Upper Lower Flammability or Explosion Limits**	:	Not available
k)	**Vapor Pressure:**	:	Not available
l)	**Vapor Density**	:	Not available
m)	**Relative Density**	:	Not available
n)	**Solubility(ies)**	:	Not available
o)	**Partition Coefficient: n-octanol/water**	:	Not available
p)	**Auto-ignition Temperature**	:	Not available
q)	**Decomposition Temperature**	:	Not available
r)	**Viscosity**	:	Not available

SECTION 10 – STABILITY AND REACTIVITY

a)	**Reactivity**	Not determined.
b)	**Chemical Stability**	Stable under standard use and storage conditions.
c)	**Possibility of Hazardous Reactions**	Not determined
d)	**Conditions to Avoid**	Not determined
e)	**Incompatible Materials**	Strong oxidizers.
f)	**Hazardous Decomposition Products**	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides, nitrogen oxides, and hydrogen chloride.

SECTION 11 – TOXICOLOGICAL INFORMATION

a)	**Likely Routes of Exposure**	Inhalation, eye/skin contact, ingestion & injection
b)	**Symptoms related to the physical, chemical and toxicological characteristics**	None anticipated from normal handling of this product. Aqueous solutions of the active ingredient, ondansetron hydrochloride, are reported to be severely irritating/corrosive to the skin. Inadvertent contact of this product with skin may produce mild irritation. are reported to be a severely irritating to the eyes. Inadvertent contact of this product with eyes or mucus membranes may produce irritation.
c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	Carcinogenic effects were not seen in 2-year studies in rats and mice with oral ondansetron dosages up to 10 and 30 mg/kg per day, respectively.

d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Ondansetron Hydrochloride Dihydrate	LD50	Oral	Rat Dog	95 mg/kg >45 mg/kg
Ondansetron Hydrochloride Dihydrate	LD50	Intravenous	Rat Dog	20.1 mg/kg >15 mg/kg

Reproductive Effects: None anticipated from normal handling of this product. Oral administration of ondansetron at dosages up to 15 mg/kg per day did not affect fertility or general reproductive performance of male and female rats. Reproduction studies in pregnant rats and rabbits using intravenous dosages up to 4 mg/kg per day have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron.

e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

SECTION 12 – ECOLOGICAL INFORMATION

a)	**Ecotoxicity**	Not available
b)	**Persistence and degradability**	Not available
c)	**Bioaccumulative potential**	Not available
d)	**Mobility in soil**	Not available
e)	**Other Adverse Effects**	Not available

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

SECTION 14 – TRANSPORTATION INFORMATION

a)	**UN Number**	Not available
b)	**UN Proper Shipping Name**	Not available
c)	**Transport Hazard Class(es)**	Not available
d)	**Packing Group**	Not available
e)	**Environmental Hazards**	Not available
f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not available
g)	**Special Precautions**	Not available

DOT: Not dangerous goods
ICAO/IATA: Not dangerous goods
IMDG: Not dangerous goods

SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:
RCRA Status-Not Listed

SECTION 16 – OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)