SAFETY DATA SHEET

Ondansetron Oral Solution, USP (4 mg/5 mL)

1. IDENTIFICATION

Product identifier: Ondansetron Oral Solution, USP (4 mg/5 mL)
Product Codes: NDC 0121-0882-51

Supplier Name and Address:	PAI Pharma 1700 Perimeter Road Greenville, SC 29605
Telephone number:	(864) 277-7282
Emergency phone number:	CHEMTREC 800-424-9300

Recommended use: Human drug
Restrictions on use: Prescription use only

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Ondansetron Hydrochloride	99614-01-4	0.1%
Fructose	57-48-7	Proprietary
Hydroxyethyl cellulose	9004-62-0	Proprietary
Sodium Benzoate	532-32-1	0.1-1%
Citric Acid	77-92-9	0.1-1%
Strawberry Flavor	Mixture	Proprietary
Sodium Citrate Dihydrate	6132-04-3	Proprietary
Water	7732-18-5	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or other symptoms occur, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause effects as seen in clinical use including headache, flushing, constipation, irregular heartbeat and hypersensitivity reactions.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and **c**ollect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Ondansetron Hydrochloride	None Established
Fructose	None Established
Hydroxyethyl cellulose	None Established
Sodium Benzoate	None Established
Citric Acid	None Established
Strawberry Flavor	None Established
Sodium Citrate Dihydrate	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.
Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	**pH:** Not determined
Odor: Strawberry	**Color:** Colorless to slightly colored
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: Not applicable	**Particle Characteristics:** Not applicable for liquids
Flammability: Not flammable	**VOC:** Not determined
Flammable limits: LEL: None	**UEL:** None
Vapor pressure: Same as water	**Relative vapor density:** Same as water
Relative density: Not available	**Solubility(ies):** Partially soluble
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Kinematic Viscosity:** Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.

Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion
Ingestion: Swallowing may cause effects as seen in clinical use including headache, flushing, constipation, irregular heartbeat and hypersensitivity reactions.
Skin contact: May cause mild irritation.
Eye contact: May cause mild irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Ondansetron was not mutagenic in standard tests for mutagenicity.
Reproductive Toxicity: Components are not classified as reproductive toxins. In embryo-fetal development studies in rats and rabbits, pregnant animals received oral doses of ondansetron up to 15 mg/kg/day and 30 mg/kg/day, respectively, during the period of organogenesis. With the exception of a slight decrease in maternal body weight gain in the rabbits, there were no significant effects of ondansetron on the maternal animals or the development of the offspring. In a pre-and postnatal developmental toxicity study, pregnant rats received oral doses of ondansetron up to 15 mg/kg/day from Day 17 of pregnancy to litter Day 21. With the exception of a slight reduction in maternal body weight gain, there were no effects upon the pregnant rats and the pre-and postnatal development of their offspring, including reproductive performance of the mated F1 generation. Oral administration of ondansetron up to 15 mg/kg per day did not affect fertility or general reproductive performance of male and female rats.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. Carcinogenic effects were not seen in 2-year studies in rats and mice with oral ondansetron doses up to 10 mg/kg per day and 30 mg/kg per day, respectively.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg
Ondansetron Hydrochloride: Oral rat LD50 95 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties of the mixture have not been evaluated. Releases to the environment should be avoided.
Ecotoxicity values: Ondansetron Hydrochloride: EC50 algae 0.87 mg/L/72 h; EC50 daphnia magna 28 mg/L/48h; LC50 fish 6.5 mg/L/96h.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.

Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

Issue Date: 01/26/2026 **Revision Date: New SDS** **Revision Number: 01**

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SDS Revision History: New SDS

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