Alembic Pharmaceuticals Limited

Safety Data Sheet
According to Regulation (EC) No. 1907/2006
Updated on 09-05-2023

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product name	:	Guanfacine ER Tablets 1mg, 2mg, 3mg and 4mg
CAS No.	:	-
Identified uses	:	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications
Company	:	Alembic Pharmaceuticals Limited Alembic Road, Vadodara, Gujarat, INDIA-390 003
Telephone	:	+91 - 265 - 228 0550
Fax	:	+91 - 265 - 228 1508
Emergency Phone #	:	

2. HAZARDS IDENTIFICATION

Fire and Explosion : Not available

Environment No information is available about the potential of this product to produce adverse environmental effects.

WARNINGS

Hypotension, bradycardia, syncope: Titrate slowly and monitor vital signs frequently in patients at risk for hypotension, heart block, bradycardia, syncope, cardiovascular disease, vascular disease, cerebrovascular disease or chronic renal failure. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Avoid concomitant use of drugs with additive effects unless clinically indicated. Advise patients to avoid becoming dehydrated or overheated

Most common adverse reactions (>5% and at least twice placebo rate) in fixed-dose monotherapy ADHD trials in children and adolescents (6 to 17 years): hypotension, somnolence, fatigue, nausea, and Lethargy.

Flexible dose-optimization ADHD trials in children (6 to 12 years) and adolescents (13 to 17 years): somnolence, hypotension, abdominal pain, insomnia, fatigue, dizziness, dry mouth, irritability, nausea, vomiting, and bradycardia.

Adjunctive treatment to psychostimulant ADHD trial in children and adolescents (6 to 17 years): somnolence, fatigue, insomnia, dizziness, and abdominal pain.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration	Oral LD_{50}	Dermal LD_{50}	Inhalation LC_{50}
Guanfacine ER Tablet	--	--	--	--	--

Guanfacine is a once-daily, extended-release formulation of Guanfacine hydrochloride, USP in a matrix tablet formulation for oral administration only. The chemical designation is N-amidino-2-(2, 6-dichlorophenyl) acetamide monohydrochloride. The molecular formula is C9 H9 Cl2 N3O•HCl corresponding to a molecular weight of 282.55.

4. FIRST AID MEASURES

Description of first aid measures

General advice - Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye Contact

In case of contact with contents of capsule, flush eyes with water for at least 15 minutes. Seek medical attention if irritation develops.

Skin Contact

If contents of capsule comes in contact with skin and clothing, remove contaminated clothing and wash skin thoroughly with running water for at least 15 minutes. Use soap if available Seek medical attention if irritation develops.

Inhalation

Dust containing drag substance could be inhaled if capsules are crushed or broken. If dust is inhaled, remove to fresh air. Seek medical attention.

Ingestion

In case of acute overdose by ingestion, seek immediate medical attention or contact the Poison Control Centre for further instructions

If swallowed do NOT induce vomiting.

5. FIRE-FIGHTING MEASURES

Extinguishing media:

Use carbon dioxide, dry chemical, or water spray. Water spray or fog - Large fires only.

Fire Fighting Instructions

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus, if required.

6. ACCIDENTAL RELEASE MEASURES

Environmental Precautions: Do not let product enter drains.

Methods and material for containment and cleaning up

Personal Precautions Wear protective clothing and equipment consistent with the degree of hazard.

Minor Spills

Clean up waste regularly and abnormal spills immediately.

Avoid breathing dust and contact with skin and eyes.

Wear protective clothing, gloves, safety glasses and dust respirator.

Use dry clean up procedures and avoid generating dust.

Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).

Dampen with water to prevent dusting before sweeping.

Place in suitable containers for disposal.

Major Spills

Moderate hazard.

CAUTION: Advise personnel in area.

Alert Emergency Services and tell them location and nature of hazard.

Control personal contact by wearing protective clothing.

Prevent, by any means available, spillage from entering drains or water courses.

Recover product wherever possible.

IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.

ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.

If contamination of drains or waterways occurs, advise Emergency Services.

7. HANDLING AND STORAGE

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. 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.

Guanfacine extended-release tablets USP, 1 mg are white to off white colored, round shaped tablets, debossed with 'L657' on one side and plain on other side.
Bottles of 100 tablets with child-resistant closure, NDC 62332-745-31
Bottles of 1000 tablets, NDC 62332-745-91

Guanfacine extended-release tablets USP, 2 mg are white to off white colored, caplet shaped tablets, debossed with 'L658' on one side and plain on other side.
Bottles of 100 tablets with child-resistant closure, NDC 62332-746-31
Bottles of 1000 tablets, NDC 62332-746-91

Guanfacine extended-release tablets USP, 3 mg are light green to green colored, round shaped tablets, debossed with 'L659' on one side and plain on other side.
Bottles of 100 tablets with child-resistant closure, NDC 62332-747-31
Bottles of 1000 tablets, NDC 62332-747-91

Guanfacine extended-release tablets USP, 4 mg are light green to green colored, caplet shaped tablets, debossed with 'L660' on one side and plain on other side.
Bottles of 100 tablets with child-resistant closure, NDC 62332-748-31
Bottles of 1000 tablets, NDC 62332-748-91

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Components with workplace control parameters

Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Avoid eye contact with contents of capsules. Wear safety glasses with side shields or goggles where risk of eye exposure exists.

Skin protection

Avoid skin contact with contents of capsules. Impervious gloves should be worn.

Other Equipment or Procedures

None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Guanfacine hydrochloride, USP is a white to off-white crystalline powder, sparingly soluble in water (approximately 1 mg/mL) and alcohol and slightly soluble in acetone. The only organic solvent in which it has relatively high solubility is methanol (>30 mg/mL). Each tablet contains Guanfacine hydrochloride, USP equivalent to 1 mg, 2 mg,

3 mg, or 4 mg of Guanfacine base. The tablets also contain methacrylic acid and ethyl acrylate copolymer, hypromellose, glyceryl dibehenate, microcrystalline cellulose, lactose monohydrate, fumaric acid, talc, silicon dioxide and magnesium stearate. In addition, the 3 mg and 4 mg tablets also contain FD&C Blue #2 Aluminum Lake and iron oxide yellow.

10. STABILITY AND REACTIVITY

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No carcinogenic effect of Guanfacine was observed in studies of 78 weeks in mice or 102 weeks in rats at doses up to 6.8 times the maximum recommended human dose of 0.12 mg/kg/day on a mg/m2 basis.

Mutagenesis

Guanfacine was not genotoxic in a variety of test models, including the Ames test and an in vitro chromosomal aberration test; however, a marginal increase in numerical aberrations (polyploidy) was observed in the latter study.

Impairment of Fertility

No adverse effects were observed in fertility studies in male and female rats at doses up to 22 times the maximum recommended human dose on a mg/m2 basis.

12. ECOLOGICAL INFORMATION

Toxicity

Do not discharge into sewer or waterways.

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Product

As specific country, federal, state and local environmental regulations are varied and change frequently, we recommend that you contact your local department for Health Services for information on the correct disposal of this product.

Contaminated packaging

Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

Land transport (UN): Not Regulated For Transport Of Dangerous Goods
Air transport (ICAO-IATA / DGR): Not regulated for transport of dangerous goods
Sea transport (IMDG-Code / GGVSee): Not Regulated For Transport Of Dangerous Goods

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.
Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available
Chemical Safety Assessment
No data available.

16. OTHER INFORMATION

Further 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 for technically qualified personnel. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Alembic Pharmaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.