安成國際藥業股份有限公司
TWi Pharmaceuticals, Inc.

Safety Data Sheet

Guanfacine Hydrochloride

Extended-Release Tablet (1mg, 2mg, 3mg, 4mg)

Section 1. Identification

Identification of the substance or preparation:

Common name: Guanfacine Hydrochloride Extended-Release Tablets

Description: Each tablet contains guanfacine HCl equivalent to1mg, 2mg, 3 mg, and 4 mg of guanfacine base.

Exposure Limits: n/f

Company/ undertaking identification:

Registered company name: TWi Pharmaceuticals, Inc.

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Emergency Phone Number: +866-2-26573350

Use of the substance/ preparation

Therapeutic Category: Attention Deficit Hyperactivity Disorder (ADHD)

Section 2: Hazard identification

Classification of the Substance or Mixture:

GHS Classification: category 5

Signal Word: warning

Hazard Statement: may be harmful if swallowed

Additional Hazard Information:

Adverse effects associated therapeutic use include somnolence, hypotension, fatigue, dizziness, lethargy, nausea, dry mouth. Serious adverse reactions include hypotension, bradycardia, syncope, sedation, somnolence, and cardiac conduction abnormalities.

Overdosage indicates that hypotension, drowsiness, lethargy, and bradycardia have been observed following overdose. Initial hypertension may develop early and may be followed by hypotension. Similar symptoms have been described in voluntary reports to the American Association of Poison Control Center's National Poison Data System. Miosis of the pupils may be noted on examination. No fatal overdoses of guanfacine have been reported in published literature.

Section 3. Composition/Information on Ingredients

	CAS No.	Percentage (%)
Guanfacine Hydrochloride	029110-48-3	Less than 2%
Non-Hazardous Ingredients	-	More than 98%

Section 4. First aid measures

Overdose treatment:

Consult a Certified Poison Control Center by calling 1-800-222-1222 for up to date guidance and advice.

Management of guanfacine extended-release tablets overdose should include monitoring for and the treatment of initial hypertension, if that occurs, as well as hypotension, bradycardia, lethargy and respiratory depression. Children and adolescents who develop lethargy should be observed for the development of more serious toxicity including coma, bradycardia and hypotension for up to 24 hours, due to the possibility of delayed onset hypotension.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Section 5. Fire-fighting measures

Fire and Explosion Hazards: No apparent fire or explosion hazards exist for the product, although the packaging is combustible.

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6. Accidental release measures

Spill Response:

Wipe up spillage or collect spillage tablets using a suitable cleaner. Place spillage in appropriately-labelled container for disposal. Wash spill site with mild soap and water.

Section 7. Handling and storage

Handling: Wash hands and other exposed areas with mild soap and water before eat, drink or smoke and when leaving work.

Storage: Store at 20° to 25℃ (68° to 77℉). Keep container closed when not in use.

Storage - away from: Strong bases. Strong acids. Sources of ignition. Direct sunlight.

Section 8. Exposure controls/personal protection

Personal protection: Avoid all unnecessary exposure.

- Hand protection : In case of repeated or prolonged contact wear gloves.

- Eye protection : Chemical goggles or safety glasses.

Section 9. Physical and chemical properties

Appearance:

	1mg	**2mg**	**3mg**	**4mg**
Color	White	White	Blue	Blue
Sharpe	Round	Caplet	Round	Caplet
Form	Tablet	Tablet	Tablet	Tablet
Debossment (top/bottom)	A533/ 1 mg	A534/ 2 mg	A536/ 3 mg	A538/ 4 mg

Molecular formula: mixture that contains guanfacine hydrochloride, USP in 0.57%, 0.91%, 1.71% and 1.82% for guanfacine hydrochloride Extended-Release Tablets 1mg, 2mg, 3mg and 4mg respectively.

Molecular weight: mixture

Section 10. Stability and reactivity

Chemical stability: Stable under recommended storage conditions.

Hazardous reactions: Not established.

Conditions to avoid: Extremely high or low temperatures. Direct sunlight.

Materials to avoid: Strong bases. Strong acids.

Hazardous decomposition products: Fumes

Section 11. Toxicological information

Rat oral LD 50[mg/kg]: 142 mg/kg in pure form of guanfacine hydrochloride. Each tablet contains less than 2% of guanfacine hydrochloride.

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/m 2 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/m 2 basis.

Section 12. Ecological information
Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Section 13. Disposal considerations
General: Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.
Section 14. Transport information
This material is not a dangerous good for the purpose of transportation.
Section 15. Regulatory information
This product is exempt from the requirements of the US OSHA Standard (29 CFR 1910.1200 (b)(6)(vii)).
Section 16. Other information
Revision : March 17, 2016