

Safety Data Sheet

Diltiazem Hydrochloride Extend-Release Capsule, USP, 120mg, 180mg, 240mg, 300mg, 360mg

SECTION 1 IDENTIFICATION

Product identifier	Diltiazem Hydrochloride Extend-Release Capsule, USP, 120mg, 180mg, 240mg, 300mg, 360mg
Recommended use	Oral (Once-a-Day Dosage)
Manufacturer	
Company name	TWi Pharmaceuticals, Inc.
Address	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
Telephone	886-2-26573350
Fax	886-2-26573391
E-mail address	QA.Service@twipharma.com
Emergency phone number	1-844-518-2989

SECTION 2 HAZARD IDENTIFICATION

Physical hazards	Not classified.
Hazard statement	Harmful if swallowed. May cause harm to the unborn child

Additional Hazard Information

Short Term	May cause eye irritation (based on components). Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
Long Term	Animal studies indicate that this material may cause adverse effects on the fetus.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Exposure Limit	CAS#
Diltiazem Hydrochloride	Not founded	33286-22-5
Non-hazardous excipients	Not founded	-

SECTION 4 FIRST-AID MEASURES

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Skin contact	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
Eye contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention

SECTION 5 FIRE-FIGHTING MEASURES

Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Fire Fighting Procedures	During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazards from combustion products	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards	Not applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly
Measures for Environmental Protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills emergency	Non-essential personnel should be evacuated from affected area. Report situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7 HANDLING AND STORAGE

General Handling	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.
Storage Conditions	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment	
Hands	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical state/ Form	Capsule

SECTION 10 STABILITY AND REACTIVITY

Stable under normal conditions of use.

SECTION 11 TOXICOLOGICAL INFORMATION

Acute toxicity	Not classified
LD50 and LC50 Data	Not available
Respiratory or skin sensitization	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Teratogenicity	Not available

SECTION 12 ECOLOGICAL INFORMATION

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose of waste in accordance with all applicable laws and regulation.

SECTION 14 TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is A205231

SECTION 16 OTHER INFORMATION

No information found.

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Disclaimer	TWi Pharmaceutical, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.