Safety Data Sheet

Product Name: Theophylline Extended Release Tablet
Strength: 300 mg & 450 mg
Pack Size: HDPE Bottle: 100's

Revision No.: 00

EMERGENCY OVERVIEW

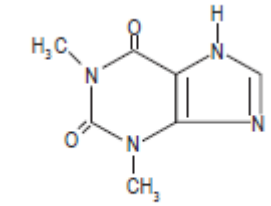
Each Theophylline Extended Release Tablet intended for oral administration contains Theophylline and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product Name: Theophylline Extended Release Tablet

Chemical Name: 1H-Purine-2, 6-dione, 3,7-dihydro-1, 3-dimethyl-, and is represented by the following structural formula:



$C_7H_8N_4O_2$ M.W. 180.17.

Manufacturer / supplier identification

Company:	**Zydus Lifesciences Ltd., Matoda, India**
Address:	Zydus Lifescience Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
US Customer Service:	
Recommended use / Therapeutic Category	Theophylline extended-release tablets are indicated for the treatment of the symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis.
Restriction on Use / Contraindications:	Theophylline extended-release tablets are contraindicated in patients with a history of hypersensitivity to theophylline or other components in the product.

Safety Data Sheet

Product Name: Theophylline Extended Release Tablet
Strength: 300 mg & 450 mg
Pack Size: HDPE Bottle: 100's

Revision No.: 00

Section 2. Hazard(s) Identification

	Taking theophylline extended-release tablets immediately after a high-fat content meal may result in a somewhat higher Cmax and delayed Tmax and somewhat greater extent of absorption. However, the differences are usually not great and this product may normally be administered without regard to meals.
Dose and Administration	Theophylline extended-release tablets are recommended for chronic or long-term management and prevention of symptoms and not for use in treating acute symptoms of asthma and reversible bronchospasm.
Adverse Effects	Adverse reactions associated with theophylline are generally mild when peak serum theophylline concentrations are < 20 mcg/mL and mainly consist of transient caffeine-like adverse effects such as nausea, vomiting, headache and insomnia. When peak serum theophylline concentrations exceed 20 mcg/mL, however, theophylline produces a wide range of adverse reactions including persistent vomiting, cardiac arrhythmias and intractable seizures which can be lethal. The transient caffeine-like adverse reactions occur in about 50% of patients when theophylline therapy is initiated at doses higher than recommended initial doses (e.g.,> 300 mg/day in adults and > 12 mg/kg/day in children beyond 1 year of age). During the initiation of theophylline therapy, caffeine-like adverse effects may transiently alter patient behavior, especially in school age children, but this response rarely persists. Initiation of theophylline therapy at a low dose with subsequent slow titration to a predetermined age-related maximum dose will significantly reduce the frequency of these transient adverse effects.

Overdosage	The chronicity and pattern of theophylline overdosage significantly influences clinical manifestations of toxicity, management and outcome. There are two common presentations: (1) acute overdose, i.e., ingestion of a single large excessive dose (> 10 mg/kg) as occurs in the context of an attempted suicide or isolated medication error and (2) chronic overdosage, i.e., ingestion of repeated doses that are excessive for the patient's rate of theophylline clearance. The most common causes of chronic theophylline overdosage include patient or care giver error in dosing, healthcare professional prescribing of an excessive dose or a normal dose in the presence of factors known to decrease the rate of theophylline clearance and increasing the dose in response to an exacerbation of symptoms without first measuring the serum theophylline concentration to determine whether a dose increase is safe.
Pregnancy Comments	There are no adequate and well-controlled studies in pregnant women. Theophylline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Pregnancy Category	Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Theophylline	150 mcg/day	58-55-9
Inactive ingredients:		
Lactose monohydrate	Not Found	10039-26-6
Hypromellose	Not Found	9004-65-3
Povidone K-3o	Not Found	9003-39-8
Magnesium stearate	Not Found	557-04-0

Section 4. First -aid measures

In Case of Inhalation	Move to fresh air. Call a physician immediately.
In Case of Skin Contact	Rinse immediately with plenty of water and seek medical advice.
In Case of Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician
Section 5. Fire -fighting measures	
Protective equipment	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
Suitable extinguishing media	Use dry chemical, CO2, water spray or "alcohol" foam
Section 6. Accidental release measure	
Personal precautions & Protective equipment	Use personal protective equipment.
Environmental precautions:	Prevent product from entering drains.
Methods and material for containment and cleaning up:	Sweep up and shovel into suitable containers for disposal.
Section 7. Handling and Storage	
Handling	Use only in area provided with appropriate exhaust ventilation.
Storage	Room Temperature
Safe handling advice	Wear personal protective equipment.
Technical measures/storage conditions	Keep containers tightly closed in a cool, well-ventilated place.
Incompatible products:	Oxidising and spontaneously flammable products.
Section 8. Exposure control / Personal Protection	
General protective and hygienic measures	Handle in accordance with good industrial hygiene and safety practice.
Eye Protection	Safety glasses with side-shields
Protection of hands	PVC or other plastic material gloves
Skin and body protection	Usual safety precautions while handling the product will provide adequate protection against this potential effect.
Respiratory protection	Breathing apparatus only if aerosol or dust is formed.
Section 9. Physical and chemical properties	
Physical States / Description	Description of Theophylline Extended Release Tablet 300 is White to off-white, capsule shaped, biconvex, uncoated tablet,

	debossed with '7' and '28' on either side of score on one side and plain on the other side. Description of Theophylline Extended Release Tablet 450 mg is White to off-white, capsule shaped, biconvex, uncoated tablet, debossed with '7' and '29' on either side of score on one side and plain on the other.		
Solubility / Miscibility in water	Soluble	**Decomposition Temperature:**	No Data
Molecular weight	180.2	**Melting Point**	270-274
Evaporation rate	No Data	**Vapour density**	No Data
Reactivity in water	No Data	**Vapour pressure**	No Data
% Volatile by volume	No Data	**Specific gravity**	No Data

Section 10. Stability and Reactivity

Stability	Stable under recommended storage conditions.
Polymerization	None under normal processing.
Hazardous decomposition products:	Nitrogen oxides (NOx)/ammonia
Materials to avoid:	Strong oxidizing agents.
Condition to avoid	Exposure to air or moisture over prolonged periods

Section 11. Toxicological information

Chronic toxicity:	Chronic exposure may cause nausea and vomiting, higher exposure causes unconsciousness.
Local effects:	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.
Specific effects:	May include moderate to severe erythema (redness) and moderate edema (raisedskin), nausea, vomiting, headache.

Section 12. Ecological information

Toxicity: Aquatic toxicity	May cause long-term adverse effects in the aquatic environment.

Safety Data Sheet

Product Name: Theophylline Extended Release Tablet
Strength: 300 mg & 450 mg
Pack Size: HDPE Bottle: 100's

Revision No.: 00

Section 13. Disposal Consideration

Dispose in accordance with local, state, and federal regulations

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

Under Approval

Section 16. Other information

None

Date of issue: 28/01/24 **Supersedes edition:** New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.