Safety Data Sheet
Triamterene and Hydrochlorothiazide Capsules, USP
Strength: 37.5 mg /25 mg
Pack Size: 100's, 500's and, 1000's Capsules per bottle and blister cartons of 100 (10 X 10) Unit-dose Capsules.

Revision No.: 00

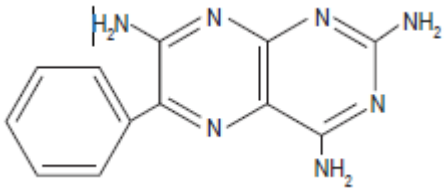
EMERGENCY OVERVIEW

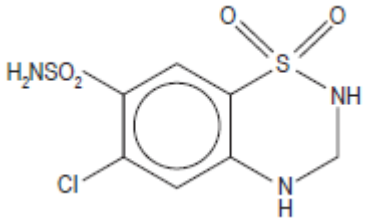
Each Triamterene and Hydrochlorothiazide Capsules, USP intended for oral administration contains Triamterene and Hydrochlorothiazide and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product Name:	Triamterene and Hydrochlorothiazide Capsule, USP
Formula:	NA
Chemical Name:	2, 4,7-triamino-6-phenylpteridine AND 6-chloro-3,4-dihydro-2H-1,2,4, benzothiadiazine-7-sulfonamide 1,1-dioxide. Hydrochlorothiazide, USP





Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd., Matoda, India**
Address:	Cadila Healthcare 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

Recommended use / Therapeutic Category	Triamterene and hydrochlorothiazide Capsule, USP may be used alone or in combination with other antihypertensive drugs, such as beta-blockers. Since triamterene and hydrochlorothiazide Capsule, USP may enhance the actions of these drugs, dosage adjustments may be necessary.
Restriction on Use / Contraindications:	**Hyperkalemia** Triamterene and hydrochlorothiazide should not be used in the presence of elevated serum potassium levels (greater than or equal to 5.5 mEq/liter). If hyperkalemia develops, this drug should be discontinued and a thiazide alone should be substituted. **Antikaliuretic Therapy or Potassium Supplementation** Triamterene and hydrochlorothiazide should not be given to patients receiving other potassium-conserving agents such as spironolactone, amiloride hydrochloride or other formulations containing triamterene. Concomitant potassium supplementation in the form of medication, potassium-containing salt substitute or potassium-enriched diets should also not be used. **Impaired Renal Function** Triamterene and hydrochlorothiazide is contraindicated in patients with anuria, acute and chronic renal insufficiency or significant renal impairment. **Hypersensitivity** Triamterene and hydrochlorothiazide should not be used in patients who are hypersensitive to triamterene or hydrochlorothiazide or other sulfonamide-derived drugs.
Section 2. Hazard(s) Identification	
Dose and Administration	The usual dose of triamterene and hydrochlorothiazide Capsule, 37.5 mg/25 mg is one or two Capsule daily, given as a single dose, with appropriate monitoring of serum potassium The usual dose of triamterene and hydrochlorothiazide Capsule, 37.5/25 mg is one Capsule daily, with appropriate monitoring of serum. Clinical experience with the administration of two 37.5 mg/25 mg (37.5 mg triamterene and 25 mg hydrochlorothiazide) Capsule daily in divided Doses (rather than as a single dose) suggests an increased risk of electrolyte imbalance and renal dysfunction. Patients receiving 25 mg hydrochlorothiazide who become hypokalemic may be transferred to triamterene and hydrochlorothiazide Capsule, 37.5 mg/25 mg directly. In patients requiring hydrochlorothiazide therapy and in whom hypokalemia cannot be risked therapy may be initiated with triamterene and hydrochlorothiazide Capsules, 37.5 mg/25 mg. If an optimal blood pressure response is not obtained with triamterene and hydrochlorothiazide Capsules, 37.5 mg/25 mg, the dose should be

	increased to two 37.5 mg/25 mg (37.5 mg triamterene and 25 mg hydrochlorothiazide) Capsules daily as a single dose daily. If blood pressure still is not controlled, another antihypertensive agent may be added
Adverse Effects	Side effects observed in association with the use of triamterene and hydrochlorothiazide Capsules, other combination products containing triamterene/hydrochlorothiazide, and products containing triamterene or hydrochlorothiazide include the following: **Gastrointestinal**: jaundice (intrahepatic cholestatic jaundice), pancreatitis, nausea, appetite disturbance, taste alteration, vomiting, diarrhea, constipation, anorexia, gastric irritation, Cramping. **Central Nervous System**: drowsiness and fatigue, insomnia, headache, dizziness, dry mouth, depression, anxiety, vertigo, restlessness, paresthesias. **Cardiovascular**: tachycardia, shortness of breath and chest pain, orthostatic hypotension (may be aggravated by alcohol, barbiturates or narcotics). **Renal**: acute renal failure, acute interstitial nephritis, renal stones composed of triamterene in association with other calculus materials, urine discoloration. **Hematologic**: leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia, hemolytic anemia and megaloblastosis. **Ophthalmic**: xanthopsia, transient blurred vision. Hypersensitivity: anaphylaxis, photosensitivity, rash, urticaria, purpura, necrotizing angiitis (vasculitis, cutaneous vasculitis), fever, respiratory distress including pneumonitis. **Other**: muscle cramps and weakness, decreased sexual performance and

	sialadenitis. Whenever adverse reactions are moderate to severe, therapy should be reduced or Withdrawn.
Over Dose Effect	No specific data are available regarding triamterene and hydrochlorothiazide overdosage in humans and no specific antidote is available. Fluid and electrolyte imbalances are the most important concern. Excessive doses of the triamterene component may elicit hyperkalemia, dehydration, nausea, vomiting and weakness and possibly hypotension. Overdosing with hydrochlorothiazide has been associated with hypokalemia, hypochloremia, hyponatremia, dehydration, lethargy (may Progress to coma) and gastrointestinal irritation. Treatment is symptomatic and supportive. Therapy with triamterene and hydrochlorothiazide should be discontinued. Induce emesis or institute gastric lavage. Monitor serum electrolyte levels and fluid balance. Institute Supportive measures as required to maintain hydration, electrolyte balance, respiratory, cardiovascular and renal function.
Contraindications	**Hyperkalemia** Triamterene and hydrochlorothiazide should not be used in the presence of elevated serum potassium levels (greater than or equal to 5.5 mEq/liter). If hyperkalemia develops, this drug should be discontinued and a thiazide alone should be substituted. **Antikaliuretic Therapy or Potassium Supplementation** Triamterene and hydrochlorothiazide should not be given to patients receiving other potassium-conserving agents such as spironolactone, amiloride hydrochloride or other formulations containing triamterene. Concomitant potassium supplementation in the form of medication, potassium-containing salt substitute or potassium-enriched diets should also not be used. **Impaired Renal Function** Triamterene and hydrochlorothiazide is contraindicated in patients with anuria, acute and chronic renal insufficiency or significant renal impairment. **Hypersensitivity** Triamterene and hydrochlorothiazide should not be used in patients who are hypersensitive to triamterene or hydrochlorothiazide or other sulfonamide-derived drugs.

Pregnancy Comments	Triamterene and Hydrochlorothiazide Animal reproduction studies to determine the potential for fetal harm by triamterene and hydrochlorothiazide have not been conducted. Nevertheless, a One Generation Study in the rat approximated triamterene and hydrochlorothiazide's composition by using a 1:1 ratio of triamterene to hydrochlorothiazide (30:30 mg/kg/day). There was no evidence of teratogenicity at those doses that were, on a body-weight basis, 15 and 30 times, respectively, the MRHD, and, on the basis of body-surface area, 3.1 and 6.2 times, Respectively, the MRHD. The safe use of triamterene and hydrochlorothiazide in pregnancy has not been established since there are no adequate and well controlled studies with triamterene and Hydrochlorothiazide in pregnant women. Triamterene and hydrochlorothiazide should be used during pregnancy only if the potential benefit justifies the risk to the fetus. Triamterene Reproduction studies have been performed in rats at doses as high as 20 times the Maximum Recommended Human Dose (MRHD) on the basis of body-weight, and 6 times the MRHD on the basis of body-surface area without evidence of harm to the fetus due to triamterene. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Pregnancy Category	C

Section 3. Composition / information on ingredients		
Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Triamterene	Not Found	396-01-0
Hydrochlorothiazide	Not Found	58-93-5
Inactive ingredients:		
Microcrystalline Cellulose	Not Found	9004-34-6
Hypromellose 3 CPS 2910	Not Found	9004-65-3
Croscarmellose Sodium	Not Found	7811-65-7
Colloidal Silicon Dioxide	Not Found	112945-52-5
Magnesium Stearate	Not Found	557-04-0
Size "4" empty hard gelatin capsule with yellow opaque cap/white opaque body having imprinting "855" on cap	Not Found	NA

Section 4. First -aid measures

General

- **After inhalation:**
  Move to fresh air in case of accidental inhalation. Assure fresh air breathing.
- **After skin contact:**
  Rinse skin with water/shower
- **After eye contact:**
  Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:**
  Rinse mouth out with water
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed-** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.

Overdose Treatment	Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.
Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted
Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.
Section 7. Handling and Storage	
Storage:	Store at 20º to 25º C (68º to 77º F) Protect from light. Dispense in a tight, light-resistant container as defined in the

	USP. **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.

Section 8. Exposure controls / personal protection	
Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Section 9. Physical and chemical properties	

Appearance	Description of **Triamterene and Hydrochlorothiazide Capsules, USP 37.5mg/25mg** is yellow to yellow colored powder fill in size "4" empty hard gelatin capsules having yellow opaque colored cap imprinted with "855" in black ink & white opaque colored body.

Solubility	Not available	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in Formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available
Information on toxicological effects	
Acute toxicity	Not available
Further information	Not available
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.

Section 13. Disposal Consideration	
	Dispose the waste in accordance with all applicable Federal, State and local laws.
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 / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA & the ANDA Number is 208360
Section 16. Other information	
	None

Date of issue: 11/02/20 **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.