Safety Data Sheet

Valsartan Tablets USP.

Strength: 40 mg, 80 mg, 160 mg and 320 mg

Pack Size: 40 mg HDPE Bottle 30's
80 mg, 160 mg, 320 mg : HDPE Bottle 90's

EMERGENCY OVERVIEW

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

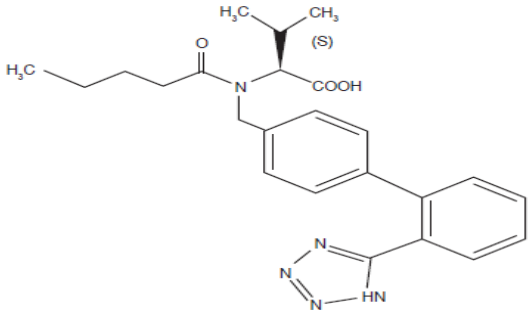
Section 1. IDENTIFICATION

Identification of the product

Product Name: **Valsartan Tablet USP**

Formula: $C_{24}H_{29}N_5O_3S$

Chemical Name:



Manufacturer / supplier identification

Company:	**Zydus Pharmaceuticals Ltd., SEZ, Matoda, India**
Address:	Zydus Pharmaceuticals Limited, Sub Plot No.21, Pharmez-SEZ Sarkhej-Bavla N.H. No. 8A, Near Village Matoda, Tal: Sanand, Dist. Ahmedabad-382213, Gujarat, India.
Contact for information:	Tel: +91-2717690241
Emergency Telephone No.	Tel: +91-2717690300
Recommended use / Therapeutic Category	Valsartan, USP is a nonpeptide, orally active and specific angiotensin II receptor blocker acting on the AT1 receptor subtype. Indicated for the treatment of Hypertension, Post-Myocardial Infarction and Heartfailure.
Restriction on Use / Contraindications:	Do not use in patients with known hypersensitivity to any component. Do not coadminister Aliskiren with Valsartan in patients with diabetes.

Lactation: Breastfeeding is not recommended
Pediatrics: Use of Valsartan is not recommended in children less than 1 year of age

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration

Valsartan tablets and oral suspension are not substitutable on a milligram-per-milligram basis. Do not combine two dosage forms to achieve the total dose. The systemic exposure to Valsartan (AUC) is 60% higher with the suspension compared to tablets

Use of the oral suspension is recommended:

• in pediatric patients aged 1 year to 5 years
• in patients >5 years of age who cannot swallow tablets and
• in pediatric patients for whom the calculated dose (mg/kg) does not correspond to the available tablet strengths of Valsartan

The recommended starting dose of Valsartan is 80 mg or 160 mg once daily when used as monotherapy in patients who are not volume-depleted.

Patients requiring greater reductions may be started at the higher dose. Valsartan may be used over a dose range of 80 mg to 320 mg daily, administered once a day.

Adverse Effects

- Headache
- Dizziness
- Viral Infection
- Fatigue
- Abdominal pain
- Hyperkalemia
- Increased blood creatinine

Overdosage

The most likely manifestations of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. Depressed level of consciousness, circulatory collapse and shock have been reported. If symptomatic hypotension should occur, institute supportive treatment.

Valsartan is not removed from the plasma by hemodialysis.

Valsartan was without grossly observable adverse effects at single oral doses up to 2,000 mg/kg in rats and up to 1,000 mg/kg in marmosets, except for salivation and diarrhea in the rat and vomiting in the marmoset at the highest dose (60 times and 31 times, respectively, the MRHD dose on a mg/m2 basis) (Calculations assume an oral dose of 320 mg/day and a 60 kg patient).

Pregnancy Comments	When pregnancy is detected, discontinue Valsartan as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. Advise female patients of childbearing age about the consequences of exposure to Valsartan during pregnancy. Discuss treatment options with women planning to become pregnant. Ask patients to report pregnancies to their healthcare provider as soon as possible
Pregnancy Category	Category 2

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Valsartan Tablet USPs	0.6 mg/day	137862-53-4
Inactive ingredients:		
Colloidal Silicon Dioxide	Not Found	112945-52-5, 7631-86-9
Crosspovidone	Not Found	9003-39-8
Microcrystalline Cellulose	Not Found	9004-34-6
Magnesium Stearate	Not Found	557-04-0
Opadry Yellow 03F520533 [40 mg and 160 mg]	Not Found	NA
Opadry Pink 03F540372 [80 mg]	Not Found	NA
Opadry Brown 03F565275 [320 mg]	Not Found	NA

Section 4. FIRST-AID MEASURES

In Case of Inhalation	Remove to fresh air, if not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
In Case of Skin Contact	Immediately wash skin with soap and plenty water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur, wash clothing before reuse.
In Case of Eye Contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eye examined and tested by medical person.
In Case of Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do not induce vomiting unless directed to do so by medical personnel

Section 5. FIRE-FIGHTING MEASURES

Fire Fighting instruction	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Specialhazards arising from the substance or mixture	No further relevant information available.
Extinguishing media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Section 6. ACCIDENTAL RELEASE MEASURES

Contamination and cleaning	Contain spill and collect, as appropriate.
Clean-up Procedures	Wearing appropriate protective gear as outlined under "Protective Equipment" wipe up spill and Transfer to a chemical waste container for disposable in accordance with local regulation.

Section 7. HANDLING AND STORAGE

Precaution to be taken in handling	Avoid breathing dust/ fumes/ gas/ mist/ vapour/ spray. Avoid prolong and repeated exposure.
Precaution to be taken in storing	Keep container tightly closed. Store in accordance with information listed on product insert.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Control	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
Eye Protection	Safety glasses.
Protective Gloves	Compatible chemical resistance gloves.
Other protective Clothing	Lab coat
Respiratory Equipment	NISHO Approved respirator, as condition warrant

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical States (Tablets/Description)	**40 mg**	Light yellow to yellow colored, oval shaped, beveled edge, film coated tablets debossed with "T" and "4" on either side of scoreline on one side and plain on the other side. The tablets should be free of all physical defects.
	80 mg	Light Pink to pink colored, oval shaped, beveled edge film coated tablets, debossed with "T7" on one side and plain on the other side The Tablets are free of all physical defects

160 mg	Light Yellow colored, oval shaped, beveled edge film coated Tablets, debossed with "277" on one side and plain on the other side. The tablets are free of all physical defects.
320 mg	Brown colored, oval shaped beveled edge film coated tablets, debossed with "278" on one side and plain on the other side. The Tablets are free of all physical defects.

Solubility in water	No Data	**Decomposition Temperature:**	No Data
Boiling point	No Data	**Melting Point**	No Data
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	This material is stable of store in accordance with information listed on product insert
Condition to avoid	No data available
Incompatibles	Strong oxidizing agents

Section 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects	The toxicological effects of this product have not been thoroughly studied. Valsartan - Toxicity Data: Oral TDLO (rat): 112 mg/kg/2W (intermittent); Oral TDLO (human): 48mg/kg/6W (intermittent); Oral TDLO (mouse): 6000 mg/kg/150D (intermittent);
Chronic Toxicological Effect	Valsartan - Investigated as a drug, mutagen and reproductive effector. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Valsartan RTECS Number: YV9455000

Section 12. ECOLOGICAL INFORMATION

Toxicity	Avoid release into environment. Run off fire control or dilution water may cause pollution

Section 13. DISPOSAL CONSIDERATION

Waste Disposal Method: 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

Approved by USFDA & the ANDA Number is 218991.

Section 16. OTHER INFORMATION

None

Date of issue: 28/08/24 **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.