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SAFETY DATA SHEET

Section 1: Identification	
Material	**Zafirlukast Tablets 10 mg and 20 mg**
Other means of identification	**Zafirlukast Tablets**
Recommended use	Pharmaceutical product
Recommended restrictions	NA
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard Classification:	Aquatic Toxicity (Chronic), Category 4
Label Elements	
GHS Signal Word:	**None**
GHS Hazard Phrases:	H413: May cause long lasting harmful effects to aquatic life.
GHS Precaution Phrases:	P273: Avoid release to the environment.
GHS Response Phrases:	No phrases apply.
GHS Storage and Disposal Phrases:	Please refer to Section 7 for Storage and Section 13 for Disposal information
Adverse Human Health Effects and Symptoms:	Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation, ingestion, or skin absorption. May cause eye, skin, or respiratory system irritation. May cause long lasting harmful effects to aquatic life. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.
Section 3: Composition / Information on Ingredients	
Active Ingredient	
Zafirlukast	
CAS	107753-78-6
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 of water for at least 20 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 20 minutes. Have eyes examined and tested by medical personnel.
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	
Suitable extinguishing media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
Unsuitable Extinguishing Media:	A solid water stream may be inefficient.
Flammable Properties and Hazards:	No data available.
Fire Fighting Instructions	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Further information	No data available
Section 6: Accidental Release Measures	
Protective Precautions, protective equipment and emergency procedures	Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
Environmental precautions	Take steps to avoid release into the environment, if safe to do so.
Methods and materials for containment and cleaning up	Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations
Section 7: Handling and Storage	
Precautions for safe handling	Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
Conditions for safe storage, including any incompatibilities	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Dispense in the original air-tight container.
Specific end use(s)	Zafirlukast is indicated for the prophylaxis and chronic treatment of asthma in adults and children 5 years of age and older.
Section 8: Exposure Controls/Personal Protection	
Exposure controls	
Appropriate engineering controls	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
Personal protective equipment	
Eye/face protection	Safety glasses with side-shields.
Protective Gloves:	Compatible chemical-resistant gloves
Other Protective Clothing	Lab coat
Respiratory protection	NIOSH approved respirator, as conditions warrant.

Section 9: Physical and Chemical Properties	
Information on basic physical and chemical properties	
Appearance	Tablet
Physical State	Solid
Description	**Zafirlukast Tablets 10 mg:** White to off-white, round, biconvex, film coated tablets debossed with 'V' on one side and '16' on the other side. Bottle of 60 Tablets NDC 31722-007-60 Bottle of 500 Tablets NDC 31722-007-05 Carton of 100 (10 x 10) unit-dose tablets NDC 31722-007-01 **Zafirlukast Tablets 20 mg:** White to off-white, round, biconvex, film coated tablets debossed with 'V' on one side and '17' on the other side. Bottle of 60 Tablets NDC 31722-008-60 Bottle of 500 Tablets NDC 31722-008-05 Carton of 100 (10 x 10) unit-dose tablets NDC 31722-008-01 Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Dispense in the original air-tight container.
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical stability	Stable under normal use and storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	No data available
Section 11: Toxicological Information	
Information on toxicological effects	The toxicological effects of this product have not been thoroughly studied. Zafirlukast - Toxicity Data: Oral TDLO (woman): 33.6 mg/kg/6W (intermittent); Oral TDLO (human): 2 mg/kg/3D (intermittent);
Chronic Toxicological Effects:	Zafirlukast - Investigated as a drug. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.
Section 12: Ecological Information	
Toxicity	No data available on formulated product
Persistence and degradability	No data is available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	No data available.
Other adverse effects	No data available.

Section 13: Disposal Considerations

Waste treatment methods	Dispose in accordance with local, state, and federal regulations.

Section 14: Transport Information

DOT (US)	Not dangerous goods
IMDG	Not dangerous goods
IATA	Not dangerous goods

Transport in accordance with local, state, and federal regulations.

Section 15: Regulatory Information

Other US EPA or State Lists: CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

Section 16: Other Information, including date of preparation or last revision

Issue Date: 06-10-2020

Version: 00

Further information

Revision date: New issue
Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.