

## **SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Lacosamide Tablets USP
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Hazard statements</b>	Causes serious eye irritation. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye protection / face protection.
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	Lacosamide
<b>CAS</b>	175481-36-4
Section 4: First-Aid Measures	
<b>Inhalation</b>	In case of unconsciousness place patient stably in side position for transportation
<b>Skin Contact</b>	Immediately wash with water and soap and rinse thoroughly.
<b>Eye Contact</b>	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
<b>General information</b>	Immediately remove any clothing soiled by the product. In case of irregular breathing or respiratory arrest provide artificial respiration.
Section 5: Fire-Fighting Measures	
<b>Extinguishing Media (Suitable)</b>	Use firefighting measures that suit the environment. A solid water stream may be inefficient.
<b>Special Firefighting Procedures</b>	No further relevant information available.
<b>Protective equipment</b>	No special measures required.
Section 6: Accidental Release Measures	
<b>Clean-up Methods</b>	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to local regulations.
<b>Personal Precautions:</b>	Wear protective equipment. Keep unprotected persons away.
<b>Environmental Precautions:</b>	Do not allow to enter sewers /surface or ground floor.
Section 7: Handling and Storage	
<b>Handling:</b>	No special precautions are necessary if used correctly.

<b>Storage:</b>	As per package insert label.																														
<b>Information about protection against explosions and fires</b>	No special measures required.																														
<b>Section 8: Exposure Controls/Personal Protection</b>																															
<b>Personal Protective Equipment: General protective and hygienic measures</b>	Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work Avoid contact with the eyes and skin																														
<b>Breathing equipment</b>	Not required																														
<b>Protection of hands</b>	The glove material has to be impermeable and resistant to the product /the substance/the preparation .Due to missing tests no recommendation to the glove material can be given for the product/the preparation /the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.																														
<b>Material of gloves</b>	The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.																														
<b>Penetration time of glove material</b>	The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.																														
<b>Section 9: Physical and Chemical Properties</b>																															
<b>Physical Form</b>	Tablet																														
<b>Description</b>	<p><b>Lacosamide Tablets USP, 50 mg</b> are pink colored, oval shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '12' on the other side. They are supplied as follows:</p> <table> <tr> <td>Bottle of 60 Tablets</td> <td>NDC 31722-812-60</td> </tr> <tr> <td>Bottle of 180 Tablets</td> <td>NDC 31722-812-18</td> </tr> <tr> <td>Bottle of 500 Tablets</td> <td>NDC 31722-812-05</td> </tr> <tr> <td>Blister pack of 100 (10 x 10s)</td> <td></td> </tr> <tr> <td>Unit dose tablets (Alu-Alu)</td> <td>NDC 31722-812-32</td> </tr> </table> <p><b>Lacosamide Tablets USP, 100 mg</b> are yellow colored, oval shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '13' on the other side. They are supplied as follows:</p> <table> <tr> <td>Bottle of 60 Tablets</td> <td>NDC 31722-813-60</td> </tr> <tr> <td>Bottle of 180 Tablets</td> <td>NDC 31722-813-18</td> </tr> <tr> <td>Bottle of 500 Tablets</td> <td>NDC 31722-813-05</td> </tr> <tr> <td>Blister pack of 100 (10 x 10s)</td> <td></td> </tr> <tr> <td>Unit dose tablets (Alu-Alu)</td> <td>NDC 31722-813-32</td> </tr> </table> <p><b>Lacosamide Tablets USP, 150 mg</b> are salmon colored, oval shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '14' on the other side. They are supplied as follows:</p> <table> <tr> <td>Bottle of 60 Tablets</td> <td>NDC 31722-814-60</td> </tr> <tr> <td>Bottle of 180 Tablets</td> <td>NDC 31722-814-18</td> </tr> <tr> <td>Bottle of 500 Tablets</td> <td>NDC 31722-814-05</td> </tr> <tr> <td>Blister pack of 100 (10 x 10s)</td> <td></td> </tr> <tr> <td>Unit dose tablets (Alu-Alu)</td> <td>NDC 31722-814-32</td> </tr> </table>	Bottle of 60 Tablets	NDC 31722-812-60	Bottle of 180 Tablets	NDC 31722-812-18	Bottle of 500 Tablets	NDC 31722-812-05	Blister pack of 100 (10 x 10s)		Unit dose tablets (Alu-Alu)	NDC 31722-812-32	Bottle of 60 Tablets	NDC 31722-813-60	Bottle of 180 Tablets	NDC 31722-813-18	Bottle of 500 Tablets	NDC 31722-813-05	Blister pack of 100 (10 x 10s)		Unit dose tablets (Alu-Alu)	NDC 31722-813-32	Bottle of 60 Tablets	NDC 31722-814-60	Bottle of 180 Tablets	NDC 31722-814-18	Bottle of 500 Tablets	NDC 31722-814-05	Blister pack of 100 (10 x 10s)		Unit dose tablets (Alu-Alu)	NDC 31722-814-32
Bottle of 60 Tablets	NDC 31722-812-60																														
Bottle of 180 Tablets	NDC 31722-812-18																														
Bottle of 500 Tablets	NDC 31722-812-05																														
Blister pack of 100 (10 x 10s)																															
Unit dose tablets (Alu-Alu)	NDC 31722-812-32																														
Bottle of 60 Tablets	NDC 31722-813-60																														
Bottle of 180 Tablets	NDC 31722-813-18																														
Bottle of 500 Tablets	NDC 31722-813-05																														
Blister pack of 100 (10 x 10s)																															
Unit dose tablets (Alu-Alu)	NDC 31722-813-32																														
Bottle of 60 Tablets	NDC 31722-814-60																														
Bottle of 180 Tablets	NDC 31722-814-18																														
Bottle of 500 Tablets	NDC 31722-814-05																														
Blister pack of 100 (10 x 10s)																															
Unit dose tablets (Alu-Alu)	NDC 31722-814-32																														

	<p><b>Lacosamide Tablets USP, 200 mg</b> are blue colored, oval shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '15' on the other side. They are supplied as follows:</p> <p>Bottle of 60 Tablets NDC 31722-815-60          Bottle of 180 Tablets NDC 31722-815-18          Bottle of 500 Tablets NDC 31722-815-05          Blister pack of 100 (10 x 10s)          Unit dose tablets (Alu-Alu) NDC 31722-815-32</p>
<b>Section 10: Stability and Reactivity</b>	
<b>Thermal decomposition/ conditions to be avoided</b>	No decomposition if used according to specifications
<b>Conditions to avoid</b>	No further relevant information available.
<b>Incompatible materials</b>	Strong acids, strong oxidizing agents
<b>Hazardous decomposition products</b>	No dangerous decomposition products known.
<b>Section 11: Toxicological Information</b>	
<b>Additional toxicological information:</b> <b>Carcinogenic categories IARC(International Agency for research on cancer)</b> <b>NTP(National Toxicology program)</b> <b>OSHA-Ca(Occupational safety &amp; Health Administration)</b> <b>LD/LC50 values that are relevant for classification:</b>	<p>Substance is not listed.</p> <p>Substance is not listed.</p> <p>Substance is not listed.</p> <p>8 mg/kg (mouse) 3 mg/kg (rat)</p>
<b>Section 12: Ecological Information</b>	
General notes:	Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
<b>Section 13: Disposal Considerations</b>	
Waste treatment methods Recommendation:	Must not be disposed of together with household garbage. Do not allow Product to reach sewage system.
Uncleaned packaging's: Recommendation:	Disposal must be made according to official regulations.
<b>Section 14: Transport Information</b>	
UN-Number DOT,IMDG,IATA	UN2811
UN proper shipping name DOT, IMDG, IATA	Toxic solids, Organic, n.o.s (Lacosamide) Toxic SOLID, Organic. N.O.S. (Lacosamide) Toxic solid, organic, n.o.s (Lacosamide)
Transport hazard class(es)	Not regulated

DOT	
Packing group DOT,IMDG,IATA	III
<b>Section 15: Regulatory Information</b>	
No further relevant information available	
<b>Section 16: Other Information</b>	
<p><b>Issue Date : 19-02-2022</b></p> <p><b>Version : 00</b></p> <p><b>Further information</b></p> <p><b>Revision date: New issue</b></p> <p><b>Revision note: New issue</b></p> <p>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.</p> <p>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.</p>	