



| Section 1: Identification                                    |                                                                                                                                                                                                                                                                                                                                     |
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| Product Name                                                 | Sacubitril and Valsartan Tablets 24mg/26mg, 49mg/51mg and 97mg/103mg                                                                                                                                                                                                                                                                |
| Recommended use                                              | Pharmaceutical product                                                                                                                                                                                                                                                                                                              |
| Manufacturer                                                 | <b>Hetero Labs Limited, Unit-III</b><br><b>22-110, IDA, Unit III, Jeedimetla,</b><br>Hyderabad-500055, India.                                                                                                                                                                                                                       |
| Distributor                                                  | <b>Camber Pharmaceuticals, Inc.,</b> Piscataway, NJ 08854                                                                                                                                                                                                                                                                           |
| Section 2: Hazard(s) Identification                          |                                                                                                                                                                                                                                                                                                                                     |
| GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) | Acute toxicity, oral<br>Skin corrosion/irritation<br>Serious eye damage/eye irritation<br>Specific target organ toxicity, single exposure; Respiratory tract irritation                                                                                                                                                             |
| GHS Label elements, including precautionary statements       | Hazard statement(s)<br><br><u><b>Prevention</b></u><br>Avoid breathing dust/fume/gas/mist/vapours/spray<br>Wash hands thoroughly after handling<br>Do not eat, drink or smoke when using this product<br>Use only outdoors or in a well-ventilated area                                                                             |
| IF ON SKIN<br><br>IF INHALED<br><br>IF IN EYES               | Wash with plenty of soap and water<br><br>Remove victim to fresh air and keep at rest in a position comfortable for breathing<br><br>Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing<br>Rinse mouth<br>Take off contaminated clothing and wash it before reuse. |
| Storage                                                      | Store in a well-ventilated place. Keep container tightly closed.                                                                                                                                                                                                                                                                    |
| Disposal                                                     | Dispose of contents/container to in accordance with local regulation                                                                                                                                                                                                                                                                |
| Other hazards                                                | None                                                                                                                                                                                                                                                                                                                                |



| Section 3: Composition/Information on Ingredients                                 |                                                                                                                                                                                                   |
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| Ingredients                                                                       | CAS                                                                                                                                                                                               |
| Sacubitril/Valsartan                                                              | 936623-90-4                                                                                                                                                                                       |
| Crospovidone                                                                      | 9003-39-8                                                                                                                                                                                         |
| Isopropyl Alcohol                                                                 | 67-63-0                                                                                                                                                                                           |
| Low-Substituted Hydroxypropyl Cellulose                                           | 9004-64-2                                                                                                                                                                                         |
| Magnesium Stearate                                                                | 557-04-0                                                                                                                                                                                          |
| Methylene chloride                                                                | 75-09-2                                                                                                                                                                                           |
| Microcrystalline Cellulose                                                        | 9004-34-6                                                                                                                                                                                         |
| Opadry Blue                                                                       | 117698-04-1                                                                                                                                                                                       |
| Opadry Brown                                                                      | 117698-04-1                                                                                                                                                                                       |
| Opadry white                                                                      | 117698-04-1                                                                                                                                                                                       |
| Povidone,                                                                         | 9003-39-8                                                                                                                                                                                         |
| Silicon Dioxide                                                                   | 14808-60-7                                                                                                                                                                                        |
| Section 4: First-Aid Measures                                                     |                                                                                                                                                                                                   |
| <b>Eye contact</b>                                                                | Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician. |
| <b>Skin contact</b>                                                               | Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.                                                                                   |
| <b>Inhalation</b>                                                                 | Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation                                       |
| <b>Ingestion</b>                                                                  | Wash out mouth with water; Do NOT induce vomiting; call a physician                                                                                                                               |
| <b>Indication of any immediate medical attention and special treatment needed</b> | Treat symptomatically                                                                                                                                                                             |
| Section 5: Fire-Fighting Measures                                                 |                                                                                                                                                                                                   |
| <b>Suitable extinguishing media</b>                                               | Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.                                                                                                                        |
| <b>Special hazards arising from the substance or mixture</b>                      | During combustion, may emit irritant fumes.                                                                                                                                                       |
| <b>Advice for firefighters</b>                                                    | Wear self-contained breathing apparatus and protective clothing.                                                                                                                                  |



| Section 6: Accidental Release Measures                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| <b>Personal precautions, protective equipment and emergency procedures</b>                                                                                                                            | Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.                                                                                                                                                                                                                                                                                                                                    |
| <b>Environmental precautions</b>                                                                                                                                                                      | Try to prevent further leakage or spillage. Keep the product away from drains or water courses                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Methods and materials for containment and cleaning up</b>                                                                                                                                          | Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol;                                                                                                                                                                                                                                                                                                                        |
| Section 7: Handling and Storage                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Precautions for safe handling</b>                                                                                                                                                                  | Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation                                                                                                                                                                                                                                                                                                                                               |
| <b>Storage</b>                                                                                                                                                                                        | Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Specific end use(s)</b>                                                                                                                                                                            | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Section 8: Exposure Controls/Personal Protection                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Control parameters</b>                                                                                                                                                                             | <b>Components with workplace control parameters</b><br>This product contains no substances with occupational exposure limit values                                                                                                                                                                                                                                                                                                                                                   |
| <b>Engineering controls</b>                                                                                                                                                                           | Ensure adequate ventilation. Provide accessible safety shower and eye wash station                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Personal protective equipment</b><br><b>Eye protection</b><br><b>Hand protection</b><br><b>Skin and body protection</b><br><b>Respiratory protection</b><br><b>Environmental exposure controls</b> | Safety goggles with side-shields<br>Protective gloves<br>Impervious clothing<br>Suitable respirator<br>Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.                                                                                                                                                                                                                                                              |
| 9: Physical and Chemical Properties                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Physical Form</b>                                                                                                                                                                                  | Tablet                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Description</b>                                                                                                                                                                                    | <p>Sacubitril and Valsartan Tablets 24 mg/26 mg are white colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S24' on the other side.</p> <p>Bottle of 60 NDC 31722-673-60<br/>Bottle of 180 NDC 31722-673-18</p> <p>Sacubitril and Valsartan Tablets 49 mg/51 mg are blue colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S25' on the other side.</p> <p>Bottle of 60 NDC 31722-674-60<br/>Bottle of 180 NDC 31722-674-18</p> |



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|                                                             | Sacubitril and Valsartan Tablets 97 mg/103 mg are brown colored, oval shaped, film-coated tablets debossed with 'H' on one side and 'S26' on the other side.<br>Bottle of 60 NDC 31722-675-60<br>Bottle of 180 NDC 31722-675-18                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Section 10: Stability and Reactivity</b>                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Reactivity</b>                                           | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Chemical stability</b>                                   | Stable under recommended storage conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Possibility of hazardous reactions</b>                   | No data available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Conditions to avoid</b>                                  | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Incompatible materials</b>                               | Strong acids/alkalis, strong oxidising/reducing agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Hazardous decomposition products</b>                     | Under fire conditions, may decompose and emit toxic fumes.<br>Other decomposition products - no data available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Section 11: Toxicological Information</b>                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Carcinogenesis, Mutagenesis, Impairment of Fertility</b> | <p>There was no evidence of carcinogenicity when valsartan was administered in the diet to mice and rats for up to 2 years at doses up to 160 and 200 mg/kg/day, respectively. These doses in mice and rats are about 2.6 and 6 times, respectively, the maximum recommended human dose on a mg/m<sup>2</sup> basis. (Calculations assume an oral dose of 320 mg/day and a 60 kg patient.) Mutagenicity assays did not reveal any valsartan-related effects at either the gene or chromosome level. These assays included bacterial mutagenicity tests with Salmonella (Ames) and E coli; a gene mutation test with Chinese hamster V79 cells; a cytogenetic test with Chinese hamster ovary cells; and a rat micronucleus test. Valsartan had no adverse effects on the reproductive performance of male or female rats at oral doses up to 200 mg/kg/day. This dose is 6 times the maximum recommended human dose on a mg/m<sup>2</sup> basis. (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)</p> <p>Valsartan – Oral LD<sub>50</sub> &gt; 2000 mg/kg ( Rat )</p> |
| <b>Section 12: Ecological Information</b>                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Toxicity</b>                                             | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Persistence and degradability</b>                        | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Bioaccumulative potential</b>                            | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Mobility in soil</b>                                     | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Results of PBT and vPvB assessment</b>                   | PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Other adverse effects</b>                                | No data available                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |



| Section 13: Disposal Considerations           |                                                                                                                                                                                   |
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| <b>Waste treatment methods</b>                | Dispose substance in accordance with prevailing country, federal, state and local regulations                                                                                     |
| <b>Product</b>                                |                                                                                                                                                                                   |
| <b>Contaminated packaging</b>                 | Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations                                                                         |
| Section 14: Transport Information             |                                                                                                                                                                                   |
| <b>DOT (US)</b>                               |                                                                                                                                                                                   |
| Proper shipping name:                         | Not dangerous goods                                                                                                                                                               |
| UN number:                                    |                                                                                                                                                                                   |
| Class: -                                      |                                                                                                                                                                                   |
| Packing group: -                              |                                                                                                                                                                                   |
| <b>IMDG</b>                                   |                                                                                                                                                                                   |
| Proper shipping name:                         | Not dangerous goods                                                                                                                                                               |
| UN number                                     |                                                                                                                                                                                   |
| Class: -                                      |                                                                                                                                                                                   |
| Packing group: -                              |                                                                                                                                                                                   |
| <b>IATA</b>                                   |                                                                                                                                                                                   |
| Proper shipping name:                         | Not dangerous goods                                                                                                                                                               |
| UN number: -                                  |                                                                                                                                                                                   |
| Class: -                                      |                                                                                                                                                                                   |
| Packing group: -                              |                                                                                                                                                                                   |
| Section 15: Regulatory Information            |                                                                                                                                                                                   |
| <b>SARA 302 Components</b>                    | No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.                                                                           |
| <b>SARA 313 Components</b>                    | This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. |
| <b>SARA 311/312 Hazards</b>                   | No SARA Hazards                                                                                                                                                                   |
| <b>Massachusetts Right To Know Components</b> | No components are subject to the Massachusetts Right to Know Act.                                                                                                                 |
| <b>Pennsylvania Right To Know Components</b>  | No components are subject to the Pennsylvania Right to Know Act.                                                                                                                  |
| <b>New Jersey Right To Know Components</b>    | No components are subject to the New Jersey Right to Know Act                                                                                                                     |



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| <b>California Prop. 65 Components</b>                                                                                                                                                                                                                                                                                                                                                   | This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm. |
| <b>Section 16: Other Information</b>                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                         |
| <b>Issue Date : 03-06-2025</b>                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                         |
| <b>Version : 00</b>                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                         |
| <b>Further information</b>                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                         |
| <b>Revision date: NA</b>                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                         |
| <b>Revision note: NA</b>                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                         |
| <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>Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.</p>                                                                                                                                                                                           |                                                                                                                                         |