



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Trade Name</b>	Dabigatran etexilate capsules 75 mg, 110 mg and 150 mg
<b>Recommended use</b>	Pharmaceutical Product
<b>Manufacturer</b>	<b>Hetero Labs Limited, 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.</b>
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc., Piscataway, NJ 08854</b>
<b>Section 2: Hazard(s) Identification</b>	
Classification of substance or mixture	The substance is not classified ,according to the Globally Harmonized system (GHS).
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredients</b>	<b>CAS</b>
Dabigatran etexilate	211915-06-9
Hydroxypropyl Cellulose	9004-64-2
Hypromellose	9004-65-3
Sugar spheres	92004-84-7
Talc	14807-96-6
Tartaric acid	87-69-4
Iron oxide red	1309-37-1
Iron oxide yellow	1309-33-7
Titanium dioxide	13463-67-7
Black iron oxide	1317-61-9
Potassium hydroxide	1310-58-3
Propylene glycol	57-55-6
Shellac	9000-59-3
Strong ammonia solution	1336-21-6
<b>Section 4: First-Aid Measures</b>	
<b>After swallowing</b>	If symptoms persist consult doctor.
<b>Inhalation</b>	Supply fresh air; consult doctor in case of complaints.
<b>Skin Contact</b>	Generally the product does not irritate the skin.
<b>Eye Contact</b>	Rinse opened eye for several minutes under running water.
<b>Signs and symptoms</b>	May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude(weakness, exhaustion),liver damage, narcosis, reproductive effects, teratogenic effects. No further relevant information available.



Section 5: Fire-Fighting Measures	
<b>Extinguishing Media (Suitable)</b>	Use fire fighting measures that suit the environment. A solid water stream may be inefficient.
<b>Special hazards arising from the substance or mixture.</b>	No further relevant information available.
<b>Protective equipment</b>	No special measures required.
Section 6: Accidental Release Measures	
<b>Clean-up Methods</b>	Pick up mechanically.
<b>Environmental Precautions:</b>	Do not allow to enter sewers/surface or ground water.
<b>Personal precautions</b>	Not required.
Section 7: Handling and Storage	
<b>Handling: Precautions for safe handling</b>	No special measures required.
<b>Storage:</b>	No further relevant information available.
Section 8: Exposure Controls/Personal Protection	
<b>Personal Protective Equipment: General protective and hygienic measures</b>	The usual precautionary measures for handling chemicals should be followed.
<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 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 manufacturer of the protective gloves and has to be observed.
<b>Eye protection</b>	Not required.
Section 9: Physical and Chemical Properties	
<b>Physical Form</b>	Capsule
<b>Description</b>	<p>Dabigatran etexilate 75 mg capsules are cream opaque cap/cream opaque body size '2' HPMC capsules imprinted with 'H' on cap and 'D10' on body with black ink, filled with mixture of off-white to yellowish white pellets. The capsules are supplied in the packages listed:</p> <p style="text-align: right;">Unit of use bottle of 60 capsules                      NDC 31722-621-60</p> <p>Dabigatran etexilate 110 mg capsules are cream opaque cap/cream opaque body size '1' HPMC capsules imprinted with 'H' on cap and 'D16' on body with black ink, filled with mixture of off-white to yellowish white pellets. The capsules are supplied in the packages listed:</p> <p style="text-align: right;">Unit of use bottle of 60 capsules                      NDC 31722-666-60</p> <p>Blister package containing 60 capsules (10 x 6 capsule blister cards)                      NDC 31722-666-32</p>



	Dabigatran etexilate 150 mg capsules are cream opaque cap/cream opaque body size '0' HPMC capsules imprinted with 'H' on cap and 'D11' on body with black ink, filled with mixture of off-white to yellowish white pellets. The capsules are supplied in the packages listed:  Unit of use bottle of 60 capsules                      NDC 31722-622-60
<b>Section 10: Stability and Reactivity</b>	
<b>Chemical stability</b>	
<b>Thermal decomposition/conditions to be avoided</b>	No decomposition if used according to specifications.
<b>Reactivity</b>	No further relevant information available
<b>Conditions to avoid</b>	No further relevant information available.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Carbon oxides, nitrogen oxides.
<b>Section 11: Toxicological Information</b>	
<b>Additional toxicological information</b>	When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. The substance is not subject to classification.
<b>Section 12: Ecological Information</b>	
<b>Additional ecological information</b> 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>	
<b>Water treatment methods</b> <b>Recommendation</b>	Smaller quantities can be disposed of with household waste.
<b>Uncleaned packagings</b> <b>Recommendation</b>	Disposal must be made according to official regulations.
<b>Section 14: Transport Information</b>	
<b>UN-Number</b> <b>DOT,IMDG,IATA</b>	Not regulated
<b>UN-proper shipping name</b> <b>DOT,IMDG,IATA</b>	Not regulated
<b>Transport hazard class(es)</b> <b>DOT,ADN,IMDG,IATA</b> <b>Class</b>	Not regulated
<b>Packing group</b> <b>DOT,IMDG,IATA</b>	Not regulated
<b>Environmental hazards</b>	Not applicable
<b>Special precautions for user</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC code</b>	Not applicable
<b>UN "model Regulation".</b>	Not regulated



### Section 15: Regulatory Information

Carcinogenic categories	
EPA	
TLV	Substance is not listed
NIOSH-Ca	Substance is not listed
GHS label elements	Substance is not listed
Hazard pictograms	None
Signal word	None
Hazard statements	None
Chemical safety assessment	A chemical safety Assessment has not carried out.

### Section 16: Other Information

**Issue Date : 01-08-2024**

**Version : 01**

**Further information**

**Revision date: 01-08-2024**

**Revision note:** Additional strength 110 mg included.

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.

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