

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Colchicine Capsules, 0.6mg
<b>Recommended use</b>	Pharmaceutical product
<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>	May cause genetic defects
<b>Precautionary statements</b>	
<b>General</b>	Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
<b>Response</b>	IF exposed or concerned: Get medical attention
<b>Storage</b>	Store locked up
<b>Disposal</b>	Dispose of contents and container in accordance with all local, regional, national and international regulations
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Colchicine	64-86-8
Anhydrous Lactose	63-42-3
Colloidal Silicon Dioxide	7631-86-9
Empty Hard Gelatin Capsules	9000-70-8
Microcrystalline Cellulose	9004-34-6
Magnesium Stearate	557-04-0
Purified Water USP / Ph. Eur./ IH	NA
Sodium Starch Glycolate Type A USP-NF	9063-38-1
Section 4: First-Aid Measures	
<b>Eye contact</b>	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is

	<p>irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway.</p> <p>Loosen tight clothing such as a collar, tie, belt or waistband.</p> <p>In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours</p>
<b>Skin contact</b>	<p>Flush contaminated skin with plenty of water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse</p>
<b>Ingestion</b>	<p>Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.</p>
<b>Most important symptoms/effects, acute and delayed Potential acute health effects</b>	
<b>Eye contact</b>	No known significant effects or critical hazards
<b>Inhalation</b>	Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure
<b>Skin contact</b>	No known significant effects or critical hazards
<b>Ingestion</b>	No known significant effects or critical hazards
<b>Over-exposure signs/symptoms</b>	
<b>Eye contact</b>	No known significant effects or critical hazards
<b>Inhalation</b>	No known significant effects or critical hazards
<b>Skin contact</b>	No known significant effects or critical hazards
<b>Ingestion</b>	No known significant effects or critical hazards
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	
<b>Notes to physician</b>	<p>In case of inhalation of decomposition products in a fire, symptoms may be delayed.</p> <p>The exposed person may need to be kept under medical surveillance for 48 hours.</p>
<b>Specific treatments</b>	No specific treatment
<b>Protection of first-aiders</b>	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still

	present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Use an extinguishing agent suitable for the surrounding fire
<b>Unsuitable extinguishing media</b>	None known
<b>Specific hazards arising from the chemical</b>	No specific fire or explosion hazard.
<b>Hazardous thermal decomposition products</b>	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides metal oxide/oxides
<b>Special protective actions for fire-fighters</b>	No special measures are required.
<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment
<b>For emergency responders</b>	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".
<b>Environmental precautions</b>	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
<b>Methods and materials for containment and cleaning up Spill</b>	Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

## Section 7: Handling and Storage

<b>Precautions for safe handling Protective measures</b>	Put on appropriate personal protective equipment (see Section 8). Avoid exposure -obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container
<b>Advice on general occupational hygiene</b>	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

## Section 8: Exposure Controls/Personal Protection

### Control parameters Occupational exposure limits

None.

<b>Appropriate engineering controls</b>	If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits
<b>Environmental exposure controls</b>	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.
<b>Individual protection measures</b>	
<b>Hygiene measures</b>	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location
<b>Eye/face protection</b>	Safety eyewear complying with an approved standard should

	be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.						
<b><u>Skin protection</u></b>							
<b>Hand protection</b>	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated						
<b>Body protection</b>	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.						
<b>Other skin protection</b>	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.						
<b>Respiratory protection</b>	Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator						
<b>Section 9: Physical and Chemical Properties</b>							
<b>Physical Form</b>	Capsules						
<b>Description</b>	<p>Colchicine capsules, 0.6 mg are Size '4' hard gelatin capsules with Green opaque Cap imprinted with "V1" in white color and light green opaque Body imprinted with "85" in white color filled with white to off white colored granular powder.</p> <table> <tr> <td>Bottle of 30 Capsules</td><td>NDC 31722-099-30</td></tr> <tr> <td>Bottle of 100 Capsules</td><td>NDC 31722-099-01</td></tr> <tr> <td>Bottle of 1000 Capsules</td><td>NDC 31722-099-10</td></tr> </table>	Bottle of 30 Capsules	NDC 31722-099-30	Bottle of 100 Capsules	NDC 31722-099-01	Bottle of 1000 Capsules	NDC 31722-099-10
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<b>Section 10: Stability and Reactivity</b>							
<b>Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients						
<b>Chemical stability</b>	The product is stable						

<b>Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur
<b>Conditions to avoid</b>	No specific data.
<b>Incompatible materials</b>	Reactive or incompatible with the following materials: oxidizing materials
<b>Hazardous decomposition products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11: Toxicological Information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Colchicine	LD50 Oral	Rat	26 mg/kg	--

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Colchicine	Eyes - Severe irritant	Rabbit	--	72 hours 1%	--

#### Sensitization

There is no data available.

#### Carcinogenicity

There is no data available

#### Specific target organ toxicity (single exposure)

There is no data available.

#### Specific target organ toxicity (repeated exposure)

There is no data available.

#### Aspiration hazard

There is no data available

**Information on the likely routes of exposure** : Dermal contact. Ingestion

#### Potential acute health effects

**Eye contact** : No known significant effects or critical hazards

**Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure

**Skin contact** : No known significant effects or critical hazards

**Ingestion** : No known significant effects or critical hazards

#### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No known significant effects or critical hazards

**Inhalation** : No known significant effects or critical hazards

**Skin contact** : No known significant effects or critical hazards

**Ingestion** : No known significant effects or critical hazards

**Delayed and immediate effects and also chronic effects from short and long term exposure****Short term exposure****Potential immediate effects :** No known significant effects or critical hazards**Potential delayed effects :** No known significant effects or critical hazards**Long term exposure****Potential immediate effects :** No known significant effects or critical hazards**Potential delayed effects :** No known significant effects or critical hazards**Potential chronic health effects****General :** No known significant effects or critical hazards**Carcinogenicity :** No known significant effects or critical hazards**Mutagenicity :** May cause genetic defects**Teratogenicity :** No known significant effects or critical hazards**Developmental effects :** No known significant effects or critical hazards**Fertility effects :** No known significant effects or critical hazards**Numerical measures of toxicity****Acute toxicity estimates**

Route	ATE value
Oral	2600 mg/kg

**Section 12: Ecological Information****Toxicity**

There is no data available

**Persistence and degradability**

There is no data available.

**Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
Colchicine	1.3	--	Low

**Mobility in soil****Soil/water partition :** Not available.**coefficient (KOC)****Other adverse effects :** No known significant effects or critical hazards



### Section 13: Disposal Considerations

#### Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

### Section 14: Transport Information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No	No	No
Additional information	-	-	-

**AERG:** Not applicable

**Special precautions for user: Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according:** Not available.  
to Annex II of MARPOL  
73/78 and the IBC Code

### Section 15: Regulatory Information

**U.S. Federal regulations :** TSCA 8(a) CDR Exempt/Partial exemption: Not determined  
United States inventory (TSCA 8b): All components are listed or exempted

**Clean Air Act Section 112 :** Not listed  
(b) Hazardous Air  
Pollutants (HAPs)

**Clean Air Act Section 602 :** Not listed  
Class I Substances

**Clean Air Act Section 602 :** Not listed



**Class II Substances****DEA List I Chemicals****(Precursor Chemicals) : Not listed****DEA List II Chemicals****(Essential Chemicals) : Not listed****SARA 302/304****Composition/information on ingredients**

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Colchicine	0.1 - 1	Yes	=	=	=	=

**SARA 304 RQ : Not applicable.****SARA 311/312****Composition/information on ingredients**

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Colchicine	0.1 - 1	No	No	No	Yes	Yes

**State regulations****Massachusetts :** The following components are listed: Cellulose; Colchicine; Silicon dioxide**New York :** The following components are listed: Colchicine**New Jersey :** The following components are listed: Cellulose; Colchicine**Pennsylvania :** The following components are listed: Cellulose; Colchicine; Silicon dioxide**California Prop. 65****WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
Colchicine	No	Yes	No	No

**International regulations**

**International lists :** Australia inventory (AICS): All components are listed or exempted  
China inventory (IECSC): All components are listed or exempted  
Japan inventory: All components are listed or exempted  
Korea inventory: Not determined  
Malaysia Inventory (EHS Register): Not determined  
New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted  
Philippines inventory (PICCS): All components are listed or exempted  
Taiwan inventory (CSNN): Not determined

**Chemical Weapons** : Not listed  
**Convention List Schedule**

**I Chemicals**

**Chemical Weapons** : Not listed  
**Convention List Schedule**

**II Chemicals**

**Chemical Weapons**

**Convention List Schedule** : Not listed

**III Chemicals**

## Section 16: Other Information

**Issue Date : 25-03-2025**

**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.

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