SAFETY DATA SHEET

Section 1: Identification	
Material	**Temozolomide Capsules** 5 mg, 20 mg, 100 mg, 140 mg, 180 mg and 250 mg
Recommended use	Alkylatic Agent, it works by Slowing or stopping the growth of cancer cells in body.
Manufacturer	**Hetero Labs Limited Unit V,** Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Adverse Effects	The following adverse reactions have been identified during post approval use of temozolomide. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug exposure. Dermatologic disorders: Toxic epidermal necrolysis and Stevens-Johnson syndrome Immune system disorders: Allergic reactions, including anaphylaxis. Erythema multiforme, which resolved after discontinuation of temozolomide and, in some cases, recurred upon rechallenge. Hematopoietic disorders: Prolonged pancytopenia, which may result in aplastic anemia and fatal outcomes. Hepatobiliary disorders: Fatal and severe hepatotoxicity, elevation of liver enzymes, hyperbilirubinemia, cholestasis, and hepatitis Infections and infestations: Opportunistic infections including Pneumocystis pneumonia (PCP) primary and reactivated cytomegalovirus (CMV), and reactivation of hepatitis B infections including some cases with fatal outcomes, and herpes simplex encephalitis including cases with fatal outcomes. Pulmonary disorders: Interstitial pneumonitis, pneumonitis, alveolitis, and pulmonary fibrosis. Endocrine disorders: Diabetes insipidus
Overdose Effect	Doses of 500, 750, 1000, and 1250 mg/m^2 (total dose per cycle over 5 days) have been evaluated clinically in patients. Dose-limiting toxicity was hematologic and was reported with any dose but is expected to be more severe at higher doses. An overdose of 2000 mg per day for 5 days was taken by one patient and the adverse reactions reported were pancytopenia, pyrexia, multi-organ failure, and death. There are reports of patients who have taken more than 5 days of treatment (up to 64 days), with adverse

	reactions reported including bone marrow suppression, which in some cases was severe and prolonged, and infections and resulted in death. In the event of an overdose, hematologic evaluation is needed. Supportive measures should be provided as necessary.
Contraindications	Hypersensitivity Temozolomide is contraindicated in patients who have a history of hypersensitivity reaction (such as urticaria, allergic reaction including anaphylaxis, toxic epidermal necrolysis, and Stevens-Johnson syndrome) to any of its components. Temozolomide is also contraindicated in patients who have a history of hypersensitivity to dacarbazine (DTIC), since both drugs are metabolized to 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC).
Pregnancy Comments	Pregnancy Temozolomide can cause fetal harm when administered to a pregnant woman. Five consecutive days of oral temozolomide administration of 0.38 and 0.75 times the highest recommended human dose (75 and 150 mg/m^2) in rats and rabbits, respectively, during the period of organogenesis caused numerous malformations of the external and internal soft tissues and skeleton in both species. Doses equivalent to 0.75 times the highest recommended human dose (150 mg/m^2) caused embryolethality in rats and rabbits as indicated by increased resorptions. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. Women of childbearing potential should be advised to avoid becoming pregnant during therapy with temozolomide.
Pregnancy Category	D

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Temozolomide	85622-93-1
Anhydrous Lactose	63-42-3
Empty Hard Gelatin Capsule Shells Size	9000-70-8
Colloidal silica	7631-86-9
Sodium Starch Glycolate	9063-38-1
Stearic acid	57-11-4
Tartaric acid	133-37-9

Section 4: First-Aid Measures	
General After inhalation:	Move to fresh air in case of accidental inhalation. assure fresh air breathing. If there are signs of intoxication, irritation, dizziness or nausea seek medical attention
After skin contact	Rinse skin with Large Volume of water/Shoap
After eye contact	Rinse with water while holding the eyes wide open. Contact lenses should be removed
After swallowing	Rinse mouth out with water
Information for doctor: **Most important symptoms and effects, both acute and delayed-** No further relevant information available.	
Indication of any immediate medical attention and special treatment needed- No further relevant information available.	
Overdose Treatment: Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.	

Section 5: Fire-Fighting Measures	
Extinguishing media Suitable extinguishing agents	Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder
Special hazards arising from the substance or mixture	Stable under normal conditions
Advice for firefighters	Small amounts: Use normal individual fire protective equipment. Large amounts: Not
Protective equipment	Hand protection: Gloves Skin and body protection: Lab coat Respiratory protection: Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted

Section 6: Accidental Release Measures	
Environmental precautions	Do not discharge into drains or the environment, dispose to an authorised waste collection point. All personnel likely to be involved in antineoplastic (cytotoxic) spill must receive practical training in: i. Correct procedures in handling cytotoxic materials/drugs or waste in order to prevent and minimise the risk of spills. ii. The location of the spill kit in the area. iii. The arrangements for medical treatment of any affected personnel. iv. The procedure for containment of the spill, and decontamination of personnel and the environment, including the different procedures for major and minor spills. v. The procedures for waste disposal according to the nature and extent of the spill.
Methods and material for containment and cleaning up	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.
Section 7: Handling and Storage	
Storage	Store temozolomide capsule at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense the accompanying Patient Information to each patient **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.
Section 8: Exposure Controls/Personal Protection	
Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary; however it is good practice to use apron
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate
Thermal hazards	Wear appropriate thermal protective clothing, when necessary
General hygiene considerations	Keep away from foodstuffs, beverages and feed.

	Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Section 9: Physical and Chemical Properties	
Physical Form	Capsule
Description	**Temozolomide Capsules, USP** **5 mg:** Opaque green cap and opaque white body, hard gelatin capsules imprinted with '13' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-411-31 Bottles of 14 count NDC 31722-411-14 **20 mg:** Opaque yellow cap and opaque white body, hard gelatin capsules imprinted with '14' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-412-31 Bottles of 14 count NDC 31722-412-14 **100 mg:** Opaque pink cap and opaque white body, hard gelatin capsules imprinted with '15' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-413-31 Bottles of 14 count NDC 31722-413-14 **140 mg:** Opaque blue cap and opaque white body, hard gelatin capsules imprinted with '16' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-414-31 Bottles of 14 count NDC 31722-414-14

	180 mg: Opaque orange cap and opaque white body, hard gelatin capsules imprinted with '17' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-415-31 Bottles of 14 count NDC 31722-415-14 **250 mg:** Opaque, white cap and opaque white body, hard gelatin capsules imprinted with '18' on cap and 'H' on body, filled with off-white to pink or tan color granular powder. Bottles of 5 count NDC 31722-416-31 Bottles of 14 count NDC 31722-416-14 Store temozolomide capsules, USP at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Section 10: Stability and Reactivity	
Conditions to avoid	Contact with incompatible materials
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport. Chemical stability Material is stable under normal conditions
Hazardous reactions	No dangerous reaction known under conditions of normal use
Decomposition products	When heated to decomposition, emits dangerous fumes
Incompatible materials	Strong Oxidizing agent
Section 11: Toxicological Information	
General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure
Other Symptoms related to the physical, chemical and **Toxicological characteristics**	Not available
Information on toxicological effects **Acute toxicity**	LD50/oral/rat: 315 mg/kg; LD50/oral/mouse: 330 mg/kg LD50/dermal/rat: N/A; LC50/inhalation/rat: N/A.

Section 12: Ecological Information

Poorly soluble in water. No data available on ecotoxicity

Section 13: Disposal Considerations

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14: Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN

Section 15: Regulatory Information

Generic Medicine. Under Approval by USFDA & the ANDA Number is 210030

Section 16: Other Information

Issue Date : 19-02-2025

Version : 00

Further information

Revision date: New issue

Revision note: New issue

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