

**VANCOUVER GENERAL HOSPITAL
CSU PHARMACEUTICAL SCIENCES
NON-FORMULARY DRUG DATA SHEET**

DRUG NAME Azacitidine	ALTERNATE NAME VIDAZA
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MANUFACTURER Celgene Corp.

STRENGTH 100mg vial	DOSAGE FORM lyophilized powder
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INDICATIONS

- For the treatment of patients with the following FAB myelodysplastic syndrome (MDS) subtypes: Refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T) and chronic myelomonocytic leukemia (CMML)

DOSAGE AND ADMINISTRATION

- 75mg/m² SC or IV infusion daily for 7 days. Repeat cycles every 4 weeks.
- After 2 cycles, may increase dose to 100mg/m² if no beneficial effect is seen and no toxicity other than nausea and vomiting has occurred.
- Patients should be treated for a minimum of 4 to 6 cycles.

For SC administration:

- Suspension that has been stored refrigerated may be allowed to equilibrate to room temperature for 30 minutes prior to administration.
- Resuspend contents prior to administration by vigorously rolling the syringe between the palms until uniform cloudy suspension is achieved
- Rotate sites for each injection (thigh, abdomen or upper arm). New injections should be given at least one inch from an old site and never into areas where the site is tender, bruised, red or hard.
- Volumes greater than 2.5mL should be divided into multiple injections at different sites

For IV administration:

- Add to 50 to 100mL of sodium chloride 0.9% or lactated ringer's
- Administer over 10 to 40 minutes (Must be completed within 1 hour of reconstitution of vial)

Drug Preparation:

	SWFI to add	Concentration	Stability	
SC	4mL	25mg/mL	RT: 1 hour Fridge: 8 hours	A suspension will be formed (The contents will be cloudy)
IV	10mL	10mg/mL	RT: 1 hour	A solution will be formed (The contents will be clear)

KNOWN SIDE EFFECTS*

- Common (SC route): nausea, anemia, thrombocytopenia, vomiting, pyrexia, leukopenia, diarrhea, injection site erythema, constipation, neutropenia and ecchymosis
- Common (IV route): all of above including petechiae, rigors, weakness and hypokalemia.
- Neutropenia, elevated serum creatinine, renal failure, renal tubular acidosis, hypokalemia, hepatic coma

SPECIAL PRECAUTIONS ***Use cytotoxic precautions***

- Unreconstituted vials are stored at room temperature
- Premedicate for nausea and vomiting
- Incompatible with dextrose 5% in water, Hespan or solutions that contain bicarbonate
- Monitor for hematological response and renal toxicities.
- Use with caution in patients with liver impairment
- Doses may need to be adjusted based on hematology laboratory values, changes in serum bicarbonate levels, BUN or serum creatinine.
- Contraindicated in patients with advanced malignant hepatic tumors or hypersensitivity to azacitidine or mannitol.

REPORT ANY ADVERSE DRUG REACTIONS TO CSU PHARMACEUTICAL SCIENCES
JUN2010