

Table 4: Most Frequently Observed Adverse Events (≥5% in All Vidaza)* Continued

Preferred Term**	All Vidaza† (N=220)	Observation† (N=92)
At least 1 TEAE	219 (99.5)	89 (96.7)
Lymphadenopathy	21 (9.5)	3 (3.3)
Herpes simplex	20 (9.1)	5 (5.4)
Hematoma	19 (8.6)	0
Night sweats	19 (8.6)	3 (3.3)
Rales	19 (8.6)	8 (8.7)
Tachycardia	19 (8.6)	6 (6.5)
Wheezing	19 (8.6)	2 (2.2)
Cellulitis	18 (8.2)	4 (4.3)
Dysuria	18 (8.2)	2 (2.2)
Breath sounds decreased	17 (7.7)	1 (1.1)
Lethargy	17 (7.7)	2 (2.2)
Oral mucosal petechiae	17 (7.7)	3 (3.3)
Stomatitis	17 (7.7)	0
Urinary tract infection	17 (7.7)	5 (5.4)
Peripheral swelling	16 (7.3)	5 (5.4)
Dyspepsia	15 (6.8)	4 (4.3)
Hemorrhoids	15 (6.8)	1 (1.1)
Hypotension	15 (6.8)	2 (2.2)
Injection site pruritus	15 (6.8)	0
Transfusion reaction	15 (6.8)	0
Pleural effusion	14 (6.4)	6 (6.5)
Abdominal distension	13 (5.9)	4 (4.3)
Muscle cramps	13 (5.9)	3 (3.3)
Post procedural hemorrhage	13 (5.9)	1 (1.1)
Postnasal drip	13 (5.9)	3 (3.3)
Rhonchi	13 (5.9)	2 (2.2)

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Preferred Term**	All Vidaza† (N=220)	Observation† (N=92)
At least 1 TEAE	219 (99.5)	89 (96.7)
Syncope	13 (5.9)	5 (5.4)
Urticaria	13 (5.9)	1 (1.1)
Anemia aggravated	12 (5.5)	5 (5.4)
Loose stools	12 (5.5)	0
Nasal congestion	12 (5.5)	1 (1.1)
Atelectasis	11 (5.0)	2 (2.2)
Chest wall pain	11 (5.0)	0
Dry skin	11 (5.0)	1 (1.1)
Dysphagia	11 (5.0)	2 (2.2)
Dyspnea exacerbated	11 (5.0)	3 (3.3)
Hypoesthesia	11 (5.0)	1 (1.1)
Injection site granuloma	11 (5.0)	0
Injection site pigmentation changes	11 (5.0)	0
Injection site swelling	11 (5.0)	0
Mouth hemorrhage	11 (5.0)	1 (1.1)
Post procedural pain	11 (5.0)	2 (2.2)
Sinusitis	11 (5.0)	3 (3.3)
Skin nodule	11 (5.0)	1 (1.1)
Tongue ulceration	11 (5.0)	2 (2.2)

* Mean Vidaza exposure = 11.4 months. Mean time in observation arm = 6.1 months.

** Multiple reports of the same preferred terms for a patient are only counted once within each treatment group.

† Includes events from observation period only; excludes any events after crossover to Vidaza.

‡ Includes events from all patients exposed to Vidaza, including patients after crossing over from observation.

Nausea, vomiting, diarrhea, and constipation all tended to increase in incidence with increasing doses of Vidaza. Nausea, vomiting, injection site erythema, constipation, rigors, petechiae, injection site pain, dizziness, injection site bruising, anxiety, hypokalemia, insomnia, epistaxis, and rales tended to be more pronounced during the first 1-2 cycles of SC Vidaza treatment compared with later cycles of treatment. There did not appear to be any adverse events that increased in frequency over the course of treatment. There did not appear to be any relevant differences in adverse events by gender.

In clinical studies of either SC or IV Vidaza, the following serious treatment-related adverse events occurring at a rate of <5% (not described in Table 4) were reported:

Blood and lymphatic system disorders: agranulocytosis, bone marrow depression, splenomegaly.

Cardiac disorders: atrial fibrillation, cardiac failure, cardiac failure congestive, cardio-respiratory arrest, congestive cardiomyopathy.

Gastrointestinal disorders: diverticulitis, gastrointestinal hemorrhage, melena, perirectal abscess.

General disorders and administration site conditions: catheter site hemorrhage, general physical health deterioration, systemic inflammatory response syndrome.

Hepatobiliary disorders: cholecystitis

Immune system disorders: anaphylactic shock, hypersensitivity.

Infections and infestations: abscess limb, bacterial infection, blastomycosis, injection site infection, Klebsiella sepsis, pharyngitis streptococcal, pneumonia Klebsiella, sepsis, Staphylococcal bacteremia, Staphylococcal infection, toxoplasmosis.

Metabolism and nutrition disorders: dehydration.

Musculoskeletal and connective tissue disorders: bone pain aggravated, muscle weakness, neck pain.

Neoplasms benign, malignant and unspecified: leukemia cutis.

Nervous system disorders: convulsions, intracranial hemorrhage.

Psychiatric disorders: confusion.

Renal and urinary disorders: hematuria, loin pain, renal failure.

Respiratory, thoracic and mediastinal disorders: hemoptysis, lung infiltration, pneumonitis, respiratory distress.

Skin and subcutaneous tissue disorders: pyoderma gangrenosum, rash pruritic, skin induration.

Surgical and medical procedures: cholecystectomy.

Vascular disorders: orthostatic hypotension.

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