

(See CRF Completion Guide for Instructions)

Case ID:

(To be completed by Cangene Corporation)

Cangene Corporation, a subsidiary of Emergent BioSolutions Inc.

On completion, please email to pharmacovigilance@ebsi.com or fax to: 1-800-768-2281 or 1-204-275-4330

Patient Demographic Information										
Patient Initials	Date of birth (mmm/dd/yyyy) - -		Sex	Male Female	Weight					lbs kg
Ethnicity:	Hispanic or Latino Not Hispanic or Latino Unknown		Race (check all that apply)		Asian	Alaska Native		White		
			African American/Black	Pacific Islander	Unknown		Other (specify):			
			American Indian							
BAT Dosing information										
Dose	Volume	Lot Number	Rate of Infusion		Infusion Start Date/Time (mmm/dd/yyyy hh24:mm)		Infusion End Date/Time (mmm/dd/yyyy hh24:mm)			
			mL/min mL/hr		-	-	:	-	-	:
			mL/min mL/hr		-	-	:	-	-	:
			mL/min mL/hr		-	-	:	-	-	:
Vital Signs Monitoring (Pre- & Post- BAT Administration)										
Date (mmm/dd/yyyy) - -	Pre-Dose	Post-Dose (preferable during the first 6-8 hours and up to 24 hours post infusion)								
Time (hh24:mm):	:	:	:	:	:	:	:	:	:	
Temperature	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	
Blood Pressure										
Pulse (bpm)										
Date (mmm/dd/yyyy) - -	Post-Dose									
Time (hh24:mm)	:	:	:	:	:	:	:	:	:	
Temperature	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	°C °F	
Blood Pressure										
Pulse (bpm)										



Form 1 - Initial Case Report Form

BT-010

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Adverse Events							No Adverse Events Reported				
Additionally, include information on inadvertent BAT overdoses or BAT medication errors.											
Description	Onset Date & Time (mmm/dd/yyyy hh24:mm)	Serious √ if Yes (see definitions)	Use codes below			Resolved Date (mmm/dd/yyyy)	Treatment Given ¹	Abated after dose stopped or reduced?		Re-appeared after re-introduction?	
			A Severity	B Causality	C Outcome			Yes	No	Yes	No
	- - :					- -		Yes No N/A		Yes No N/A	
	- - :					- -		Yes No N/A		Yes No N/A	
	- - :					- -		Yes No N/A		Yes No N/A	
	- - :					- -		Yes No N/A		Yes No N/A	
See Definitions page	A. Severity/Intensity: 1. Mild 2. Moderate 3. Severe		B. Causality Assessment: 1. Certain 2. Probable/Likely 3. Possible			C. Outcome: 4. Unlikely 5. Conditional/Unclassified 6. Unassessable/Unclassifiable 7. Unrelated		1. Resolved 2. Resolved with Sequelae 3. Resolving/ Ongoing 4. Fatal 5. Unknown			

¹ If checked complete Concomitant Medications/Corrective Treatments section

FOLLOWING BAT ADMINISTRATION, did the patient experience any of the following reactions?							No Reactions Observed	
If any reactions were observed, the DIAGNOSIS is to be included in the Adverse Events table above.								
Description	Occurrence							
Fever /Febrile reaction >1°C over baseline	Yes	No	Unknown					
Chills/Rigors	Yes	No	Unknown					
Bradycardia < 60 bpm	Yes	No	Unknown	If 'yes'	Heart Rate:	bpm		
Tachycardia > 100 bpm	Yes	No	Unknown	If 'yes'	Heart Rate:	bpm		
Hemodynamic Instability	Yes	No	Unknown					
Allergic Reaction	Yes	No	Unknown	If 'yes', Signs & symptoms:	Anaphylaxis Urticaria Hypotension	Angioedema Bronchoconstriction Syncope	Rash Flushing Other:	
Serum sickness	Yes	No	Unknown	If 'yes', Signs & symptoms:	Polyarthralgia Lymphadenopathy	Rash Other:	Myalgia	



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Clinical Information						
Is patient symptomatic? Yes No Unknown	Onset Date & Time	(mmm-dd-yyyy hh24:mm) - - :	Neurologic Symptom Onset	(mmm-dd-yyyy) - -	Date First Sought Medical Care	(mmm-dd-yyyy) - -
Vital Signs (upon presentation):		Temperature	Blood Pressure (mmHg)	/	Heart Rate(beats/min)	Respiration Rate(breaths/min)
Date and time of exposure to botulism toxin (mmm/dd/yyyy hh:mm):		- - :	Actual	Presumed	Unknown	
Hospitalized?	Yes No	Admission date (mmm-dd-yyyy):		- -	Discharge date: - -	
Patient admitted to ICU?	Yes No	If yes, admission date (mmm-dd-yyyy):		- -	Discharge date: - -	
Patient required mechanical ventilation?	Yes No	If yes, start date (mmm-dd-yyyy):		- -	Cessation date: - -	
Diagnosis:	Botulism	Tick paralysis	Paralytic shellfish poisoning	Myasthenia gravis	Eaton-Lambert syndrome	
	Guillain-Barre syndrome	Stroke or central nervous system mass or lesion	Other (specify):			

Botulism Antitoxin (BAT) Administration Information			
Has the patient had any previous treatment with equine blood products?	Yes	No	Unknown
Were any pre-medications given? Yes No	If yes, indicate type and include details in the Concomitant Medications section below		Corticosteroid Antihistamine Analgesic/antipyretic Other (specify):

Neuromuscular Examination			Deep Tendon Reflexes		
	Right	Left		Right	Left
Proximal Upper Extremity			Biceps/Triceps		
Distal Upper Extremity			Brachial		
Proximal Lower Extremity			Patellar		
Distal Lower Extremity			Ankle		
0 = No evidence of contractility 1 = Slight contractility, no movement 2 = Full range of motion, gravity eliminated			0 = No Response 1 = Sluggish or diminished 2 = Active or expected response		
3 = Full range of motion, with gravity 4 = Full range of motion, against gravity, some resistance 5 = Full range of motion, against gravity, full resistance			3 = More brisk than expected, slightly hyperactive 4=Brisk, hyperactive, with intermittent or transient clonus		
If muscle weakness/paralysis present, describe progression:					
Ascending, ending with cranial nerves		Descending, beginning with cranial nerves		Other (specify): None Unknown	



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Symptoms (check all that apply)	Yes	No	Symptom	Yes	No
Nausea			Thick tongue		
Vomiting			Change in sound of voice		
Abdominal pain			Hoarseness		
Diarrhea			Dry Mouth		
Constipation			Dysphagia (difficulty swallowing)		
Blurred vision			Shortness of breath		
Diplopia (double vision)			Subjective weakness		
Dizziness			Fatigue		
Slurred speech			Paresthesia (abnormal sensation, e.g. numbness)		

Other (specify):

Physical Examination Findings	Yes	No		Yes	No
Alert and oriented			Pupils non-reactive		
Extra-ocular palsy (paralysis of eye muscles)			If yes, is it bilateral		
If yes, is it bilateral			Facial paralysis		
Ptosis (drooping eyelids)			If yes, is it bilateral		
If yes, is it bilateral			Palatal weakness		
Pupils dilated			If yes, is it bilateral		
If yes, is it bilateral			Impaired gag reflex		
Pupils constricted			Sensory deficit(s)		
If yes, is it bilateral			If yes, specify		

Other (specify):

Concomitant Medications/Corrective Treatments

The following medications and treatments are to be included:

- Medications in use at the time of BAT administration
- Medications given as pre-treatments to the antitoxin treatment
- Treatments of adverse events/reactions including hemodynamic instability treatments and procedures

Concomitant Medications/ Corrective Treatments	Indication	Treatment of reaction? √ if Yes	Dosage	Frequency	Route	Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)	Ongoing? √ if Yes
						- -	- -	
						- -	- -	
						- -	- -	

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Medical History				
Prior botulism diagnosis?		If yes, date (mmm/dd/yyyy)	Medications used in previous 30 days that could cause neuromuscular paralysis: Myobloc (toxin type B) Aminoglycoside (e.g.gentamicin, tobramycin) None Unknown Botox (toxin type A) Anticholinergic Other (specify):	
Yes	No Unknown			
Does the patient have prior medical history?		Yes No	If yes, provide details below	
Please include relevant medical history, risk factors for tachycardia, bradycardia, neurological impairment, hypersensitivity reactions and known allergies		Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)	Ongoing? √ if Yes
		- - Unknown	- - Unknown	
		- - Unknown	- - Unknown	
		- - Unknown	- - Unknown	
		- - Unknown	- - Unknown	
		- - Unknown	- - Unknown	
		- - Unknown	- - Unknown	

Reporting Physician/Hospital				
Treating Physician Name - Last Name, First Name		Telephone Number	Fax Number	Today's Date (mmm/dd/yyyy)
Hospital Name		City	State	ZIP Code

I have reviewed this Case Report Form and agree that the data reported are accurate, complete and legible.
Any changes or corrections are dated, initialled and explained.

Signature: _____

Date: _____ - -

Reporter's Name: _____

Role: _____

Definitions	
Severity/Intensity Assessment:	
Mild	Awareness of a sign or symptom, but subject can tolerate.
Moderate	Discomfort enough to cause interference with normal daily activity.
Severe	Resulting in an inability to do work or do usual daily activity.
Causality (Relatedness) Assessment of Adverse Event(s) (AEs):	
The evaluation of any event in relationship to drug administration.	
As per the WHO-UMC causality assessment system, the following definitions are used to assess relatedness of the adverse events:	
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake. Cannot be explained by disease or other drugs. Response to withdrawal plausible (pharmacologically, pathologically). Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon). Rechallenge satisfactory, if necessary.
Probable/Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake. Unlikely to be attributed to disease or other drugs. Response to withdrawal clinically reasonable. Rechallenge not required.
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake. Could also be explained by disease or other drugs. Information on drug withdrawal may be lacking or unclear.
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible). Disease or other drugs provide plausible explanations.
Conditional/ Unclassified	Event or laboratory test abnormality. More data for proper assessment needed, or additional data under examination.
Unassessable/ Unclassifiable	Report suggesting an adverse reaction cannot be judged because information is insufficient or contradictory. Data cannot be supplemented or verified.
Unrelated	There is no established relationship between the occurrence of an adverse event and the concomitant or previous intake of a medicinal product.
Seriousness criteria	
A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose:	
Results in death	Is life-threatening
Requires inpatient hospitalization or prolongation of existing hospitalization	Is a congenital anomaly/birth defect
Results in persistent or significant disability/incapacity	Is medically important
<p>NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.</p> <p>Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious.</p>	