Comprehensive Adverse Events and Potential Risks list (CAEPR) for Ferumoxytol (NSC 729745)

The Comprehensive Adverse Event and Potential Risks list (CAEPR) provides a single list of reported and/or potential adverse events (AE) associated with an agent using a uniform presentation of events by body system. In addition to the comprehensive list, a subset, the Specific Protocol Exceptions to Expedited Reporting (SPEER), appears in a separate column and is identified with bold and italicized text. This subset of AEs (SPEER) is a list of events that are protocol specific exceptions to expedited reporting to NCI via AdEERS (except as noted below). Refer to the 'CTEP, NCI Guidelines: Adverse Event Reporting Requirements' http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf for further clarification. *Frequency is provided based on 1726 patients*. Below is the CAEPR for Ferumoxytol.

NOTE: Report AEs on the SPEER **ONLY IF** they exceed the grade noted in parentheses next to the AE in the SPEER. If this CAEPR is part of a combination protocol using multiple investigational agents and has an AE listed on different SPEERs, use the lower of the grades to determine if expedited reporting is required.

[1]Version 2.1[1]

Adverse Events with Possible Relationship to Ferumoxytol (CTCAE 4.0 Term) [n= 1726]			Specific Protocol Exceptions to Expedited Reporting (SPEER) (formerly known as ASAEL)
Likely (>20%)	**Less Likely (<=20%)**	**Rare but Serious (<3%)**	
GASTROINTESTINAL DISORDERS			
	Constipation		
	Diarrhea		
	Nausea		
	Vomiting		
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
	Edema limbs		
	Injection site reaction		
	Non-cardiac chest pain		
IMMUNE SYSTEM DISORDERS			
	Allergic reaction[2]		
		Anaphylaxis[2]	
METABOLISM AND NUTRITION DISORDERS			
	Iron overload[3]		
NERVOUS SYSTEM DISORDERS			
	Dizziness		
	Headache		
RENAL AND URINARY DISORDERS			
		Chronic kidney disease	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
	Bronchospasm[2]		
	Cough		
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
	Pruritus[2]		
	Rash maculo-papular[2]		
	Urticaria[2]		
VASCULAR DISORDERS			
	Hypertension		
	Hypotension		

[1]This table will be updated as the toxicity profile of the agent is revised. Updates will be distributed to all Principal Investigators at the time of revision. The current version can be obtained by contacting PIO@CTEP.NCI.NIH.GOV . Your name, the name of the investigator, the protocol and the agent should be included in the e-mail.

[2]Allergic reactions frequently associated with hypersensitivity include bronchospasm (wheezing), pruritus, rash, and urticaria as well as more serious anaphylactic reactions.

[3] Do not administer Ferumoxytol to individuals known to have iron overload

Also reported on Ferumoxytol trials but with the relationship to Ferumoxytol still undetermined:

EYE DISORDERS - Blurred vision
GASTROINTESTINAL DISORDERS - Abdominal pain; Dyspepsia
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS - Chills; Fatigue; Fever
INJURY, POISONING AND PROCEDURAL COMPLICATIONS - Bruising
INVESTIGATIONS - Weight gain; Weight loss
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS - Back pain; Musculoskeletal and connective tissue disorder - Other (Muscle spasms/cramps)
NERVOUS SYSTEM DISORDERS - Dysgeusia; Peripheral sensory neuropathy; Syncope
PSYCHIATRIC DISORDERS - Confusion
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS - Dyspnea
SKIN AND SUBCUTANEOUS TISSUE DISORDERS - Hyperhidrosis

Note: Ferumoxytol in combination with other agents could cause an exacerbation of any adverse event currently known to be caused by the other agent, or the combination may result in events never previously associated with either agent.