

Tabulated list of ADRs from clinical trials

The ADRs in 586 patients treated with Polivy are presented in Table 4. The ADRs are listed below by MedDRA system organ class (SOC) and categories of frequency. The corresponding frequency category for each adverse drug reaction is based on the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$). Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.

Table 4 Tabulated list of ADRs in patients treated with Polivy in clinical trials

Infections and infestations	
Very common	pneumonia ^a , upper respiratory tract infection
Common	sepsis ^a , herpes virus infection ^a , cytomegalovirus infection, urinary tract infection ^c
Blood and lymphatic system disorders	
Very common	febrile neutropenia, neutropenia, thrombocytopenia, anaemia, leukopenia
Common	lymphopenia, pancytopenia
Metabolism and nutrition disorders	
Very common	hypokalaemia, decreased appetite
Common	hypocalcaemia, hypoalbuminemia
Nervous system disorders	
Very common	neuropathy peripheral
Common	dizziness
Eye disorders	
Uncommon	vision blurred ^b
Respiratory, thoracic and mediastinal disorders	
Very common	cough
Common	pneumonitis, dyspnoea ^c
Gastrointestinal disorders	
Very common	diarrhoea, nausea, constipation, vomiting, mucositis ^c , abdominal pain
Skin and subcutaneous tissue disorders	
Very common	alopecia ^c
Common	pruritus, skin infections ^c , rash ^c , dry skin ^c
Musculoskeletal disorders	
Common	arthralgia, myalgia ^a
General disorders and administration site conditions	
Very common	pyrexia, fatigue, asthenia
Common	peripheral edema ^c , chills
Investigations	
Very common	weight decreased
Common	transaminases increased, lipase increase ^b , hypophosphataemia
Injury, poisoning and procedural complications	
Very common	infusion related reaction

^aADR associated with fatal outcome

^bADRs observed in relapsed or refractory DLBCL only.

^cADRs observed in previously untreated DLBCL only.

The listed ADRs were observed in both previously untreated DLBCL and relapsed or refractory DLBCL except where indicated with footnotes.

Rare and very rare ADRs: none