

Tabulated list of adverse reactions

The following listing of adverse reactions is based on the clinical trial experience and are displayed by system organ class. Within the system organ classes, adverse reactions are listed under headings of the following frequency categories: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$) and uncommon ($\geq 1/1,000$ to $< 1/100$). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1. Adverse Reactions		
System Organ Class	Frequency	Adverse Reaction(s)
Infection and infestation	Very Common	Nasopharyngitis
	Common	Bronchitis, Gastroenteritis, Upper respiratory tract infection, Influenza, Sinusitis, Pharyngitis
	Uncommon	Respiratory tract infection, Vulvovaginal candidiasis, Oral Candidiasis
Nervous system disorders	Very Common	Headache
	Common	Paraesthesia
Vascular disorders	Common	Hypertension
Respiratory, thoracic and mediastinal disorders	Common	Oropharyngeal pain, Nasal congestion, Cough
Gastrointestinal disorders	Common	Anal Abscess, Anal fissure, Nausea, Dyspepsia, Constipation, Abdominal distension, Flatulence, Haemorrhoids
Skin and subcutaneous tissue disorders	Common	Rash, Pruritus, Eczema, Erythema, Night sweats, Acne
	Uncommon	Folliculitis
Musculoskeletal and connective tissue disorders	Very Common	Arthralgia
	Common	Muscle spasms, Back pain, Muscular weakness, Fatigue
General disorders and administration site conditions	Common	Pyrexia
	Uncommon	Infusion site reaction (including: Infusion site pain and Infusion site irritation), Infusion related reaction Chills, Feeling cold