

126 primary suspect cases

AEs – Subsys (fentanyl sublingual spray)

Adverse Event	Cases
Death	63
Off label use	7
Drug abuse	6
Toxicity to various agents	6
Investigation	5
Neoplasm malignant	5
Malignant neoplasm progression	5
Hospice care	4
Accidental death	4
Hospitalisation	3
Pneumonia	3
Breast cancer stage IV	2
Product packaging quantity issue	2
Terminal state	2
Breast cancer metastatic	2
Road traffic accident	2
Cardiac arrest	2
Renal failure	2
Confusional state	2
Product quality issue	2
Nausea	2
Gingival operation	1
Pelvic adhesions	1
Colon cancer stage IV	1
Lip and/or oral cavity cancer	1
Metastatic malignant melanoma	1
Colon cancer metastatic	1

Pancreatic carcinoma metastatic	1
Chemical injury	1
Craniocerebral injury	1
Breakthrough pain	1
Disease complication	1
Reaction to drug excipients	1
Metastatic neoplasm	1
Peripheral swelling	1
Metastasis	1
Parosmia	1
Oedema mouth	1
Increased upper airway secretion	1
Blood glucose abnormal	1
Drug effect incomplete	1
Pancreatic carcinoma	1
Application site pain	1
Scar	1
Skin lesion	1
Lung neoplasm malignant	1
Ill-defined disorder	1
Diplopia	1
Device malfunction	1
Ascites	1
Respiratory distress	1
Accidental overdose	1
Dysuria	1
Surgery	1
Stomatitis	1
Breast cancer female	1
Dysarthria	1

Drug dependence	1
Cellulitis	1
Hepatic failure	1
Vertigo	1
Influenza	1
Disorientation	1
Abnormal behaviour	1
Migraine	1
Lethargy	1
Burning sensation	1
Hallucination	1
Coma	1
General physical health deterioration	1
Incorrect dose administered	1
Disease progression	1
Drug hypersensitivity	1
Visual impairment	1
Dysphagia	1
Suicidal ideation	1
Completed suicide	1
Drug dose omission	1
Vision blurred	1
Loss of consciousness	1
Somnolence	1
Constipation	1
Overdose	1
Drug interaction	1
Decreased appetite	1
Back pain	1
Convulsion	1

Condition aggravated	1
Abdominal pain	1
Pruritus	1
Fall	1
Arthralgia	1
Myocardial infarction	1
Malaise	1
Dizziness	1
Vomiting	1
Fatigue	1
Dyspnoea	1
Drug ineffective	1
Hypoxic-ischaemic encephalopathy	1
Hypertensive cardiomyopathy	1
Contusion	1
Excoriation	1
Left ventricular hypertrophy	1
Unresponsive to stimuli	1
Pulmonary oedema	1
Pulmonary congestion	1
Coronary artery stenosis	1
Cardiomegaly	1
Arteriosclerosis coronary artery	1