

| <u>Adverse Events</u> | <u>Definitions</u> |
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| Abnormal dreams | Unusual or atypical dreams |
| Acute Renal Insufficiency | Aka Acute Renal Failure (ARF) or Acute Renal Injury (ARI) - means a rapidly progress loss of renal function, characterized by decrease urine production, fluid and electrolyte imbalance, increase in serum creatinine level |
| Alopecia | Loss of hair |
| Anemia | Decrease of hemoglobin in blood |
| Arthralgias | Joint pain |
| Anxiety | An abnormal and overwhelming sense of apprehension and fear often marked by physiological signs (as sweating, tension, increased pulse), by doubt concerning reality and nature of the threat, and by self-doubt about one's capacity to cope with it |
| Asthenia | Weakness, due to lack or loss of strength |
| Blood clotting | Process which involves shedding of blood and interaction of thrombin to form insoluble fibrin network |
| Cholangitis | Inflammation of bile duct or entire biliary tree |
| Cholecystitis | Inflammation of gall bladder |
| Choledocholithiasis | Presence of a stone in the common bile duct |
| Cholelithiasis | Presence of concretions in gallbladder or bile ducts |
| Chronic Renal Insufficiency | Aka Chronic Renal Failure, or Chronic Renal Disease, which is a progressive loss of renal function over period of months or years. Often present with high levels of creatinine which indicate lower glomerular filtration rate |
| Coughing | To expel air from the lungs suddenly |
| Depression | State of feeling sad, marked by inactivity, difficult with thinking, increase or decrease in appetite, feelings of dejection, hopelessness, attempt to commit suicide |
| Diabetes Mellitus | Deficiency of insulin and characterized by chronic increase in blood glucose and other long term complications |
| Diarrhea | Abnormally frequent intestinal evacuations with more or less fluid stools |
| Dizziness | Sensation of unsteadiness accompanied by feeling of movement within the head |
| Dyslipidemia | Elevation of total cholesterol, LDL and triglyceride levels |
| Emesis | Vomiting |
| Erythema | Redness |
| Fatigue | Weariness or exhaustion |
| Fever | Rise of body temperature above the normal |
| Flank pain | Pain in one side of body in the abdominal area |
| Flatulence | Presence of excessive amount of gas in stomach and intestines |
| GI intolerance | Upset stomach |
| Headache | Pain in the head |
| Hepatic flares | Sudden increase in liver enzymes |
| Hepatomegaly | Liver enlargement |
| Hyperbilirubenimia | Excess bilirubin in the blood |
| Hypercholesterolemia | Excess cholesterol in the blood |

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| Hyperpigmentation | Excess pigment in bodily part or tissue |
| Hypertension | High blood pressure |
| Hypertriglyceridemia | Excess amount of triglycerides in the blood |
| Hyperuricemia | Excess uric acid in the blood |
| Hypophosphatemia | Deficiency of phosphates in the blood |
| Impaired concentration | Difficulty in maintaining a fixed, close, undivided attention |
| Ingrown Nails | When the edge of the nail grows down and into the skin of the toe - may present as pain, redness, swelling around the nail |
| Insomnia | Trouble sleeping |
| Insulin resistance | Reduced sensitivity to insulin by body's insulin-dependence processes that result in lowered activity or increase in insulin production, often occurs in absence of diabetes |
| Jaundice | Yellowish pigment of the skin, tissues and certain body fluids caused by deposition of bile pigments |
| Lethargy | Drowsiness, state of being lazy, sluggish or indifferent |
| Lipodystrophy | Loss of fat from or deposition of fat in tissue |
| Lipohypertrophy | Lump under skin caused by accumulation of extra fat |
| Loss of appetite | Loss of desire to eat food |
| Malaise | Feeling of debility or lack of health |
| Male Gynecomastia | Excessive development of breast in male |
| Metabolic syndrome | Syndrome marked by presence of usually 3+ group of factors: High blood pressure, abdominal obesity, high triglyceride levels, low HDL levels, high fasting blood sugar, which are linked to an increased risk of cardiovascular disease and type 2 diabetes, and Alzheimer's disease. |
| Myalgia | Pain in one or more muscle |
| Myopathy | Disorder of muscle tissue or muscles |
| Nausea | A sensation of unease and discomfort in the upper stomach with an involuntary urge to vomit |
| Neurological Toxicities | Damage to the nervous system presenting symptoms from limb weakness, numbness, loss of memory/vision |
| Nightmares | Disturbing dreams |
| Oral Ulcerations | Oral sores |
| Osteopenia | Reduced bone mineral density |
| Pain (Back, leg, neck) | State of physical, emotional, or mental lack of well-being or physical, emotional, or mental uneasiness that ranges from mild discomfort or dull distress to acute often unbearable agony, may be generalized or localized |
| Pneumonia | Inflammation and consolidation of lung tissue followed by resolution, accompanied by fever, chills, cough, and difficulty in breathing |
| Prolong PR interval | Increased PR interval in heart rhythm, may increase risk of atrial fibrillation |
| Pruritus | Localized or generalized itching |
| Sneezing | A sudden violent spasmodic audible expiration of breath through the nose and mouth especially as a reflex act following irritation of the nasal mucous membrane |
| Somnolence | Quality or state of being drowsy |
| Suicidal ideation | Increase inclination to cause suicide |

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| Taste Perversion | Distorted sense of taste |
| Tinnitus | Ringin g in ears |
| Torsades de pointes | Heart arrhythmia which is characterized by fluctuation of QRS complexes |
| Vomiting | Act of disgorging contents of stomach through mouth |
| Weight change | |

| Serious Adverse Events | Definitions |
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| Birth Defects | |
| Death | |
| Fanconi syndrome | Disorder of proximal renal tubules in which certain substances (Amino acids, glucose, uric acid, phosphates) normally absorbed into bloodstream by kidneys are released into urine instead |
| Hematuria | Presence of blood or red blood cells in urine |
| Hepatic toxicity | Drug-induced liver damage which manifest as abnormal liver enzyme tests |
| Hypersensitivity syndrome | Severe, idiosyncratic multi-system reaction defined by fever, rash and internal organ involvement which may occur 1-8 weeks after exposure to drugs |
| Immune reconstitution syndrome | Collection of inflammatory disorders associated with paradoxical worsening of preexisting infectious processes following HAART initiation |
| Intracranial Hemorrhage | Bleeding within cranial vault, includes cerebral hemorrhage and subarachnoid hemorrhage |
| Lactic Acidosis | Type of metabolic acidosis caused by accumulation of lactic acid in bloodstream |
| Lipoatrophy | Loss of subcutaneous fat |
| Liver failure | Condition in which the liver fails to fulfill its function or is unable to meet the demands made on it. Anorexia, fatigue, and weakness are common symptoms of liver cell failure, whereas jaundice indicates a biliary obstruction, and fever may accompany viral or alcoholic liver diseases. |
| Mitochondrial Toxicities | Condition in which mitochondria of body's cells become damaged or decline significantly in number, often present as weakness or myopathy, peripheral neuropathy, lactic acidosis |
| Myocardial Infarction | Heart attack, often use to blood clots that block flow of blood through coronary artery |
| Nephrolithiasis | Kidney stones |
| Nephrotoxicity | Drug toxicity in kidney |
| Neural Tube Defects | Major birth defect present as abnormal of the neural tube which give rise to the central nervous system |
| Neurologic toxicities | Drug induced toxicities in the nervous system |
| Neuromuscular Weakness | Generalized weakness that affects the muscles which control respiration |
| Neutropenia | Abnormally low count of neutrophils, which is a type of white blood cells |
| Pancreatitis | Inflammation of pancreas |
| Peripheral Neuropathy | Numbness and pain in hands and feet, can also be described as tingling or burning sensation |
| Prematurity | |
| Psychosis | Mental state which cause gross distortion or disorganization of a person's mental capacity |
| QT Interval Prolongation | Heart rhythm disorder in which QT interval is longer than normal, which can cause fast and chaotic heart beats, may trigger sudden fainting spell or seizure |
| Rash | Group of spots or red, inflamed skin that is usually a symptom of an underlying condition or disorder |
| Rhabdomyolysis | Severe muscle pain that is caused by breakdown of muscle cells |

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| Seizure | Uncontrolled electrical activity in the brain, which may produce a physical convulsion, minor physical signs, thought disturbances, or a combination of symptoms |
| Steatosis | Fatty liver, collection of excessive amounts of triglycerides and other fats inside liver cells |
| Stevens-Johnson Syndrome | Rare and serious disorder in which skin and mucous membranes react severely, begins with flu-like symptoms, followed by painful red or purplish rash that spreads and blisters, eventually causing top layer of skin to die and shed, often present as medical emergency and require hospitalization |
| Stroke | Aka Cerebral vascular accident (CVA), rapid loss of brain function due to disturbance in blood supply to the brain may due to lack of blood flow caused by blockage |