# Possible Side Effects of FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, Oxaliplatin)

(Table Version Date: February 7, 2025)

| **COMMON, SOME MAY BE SERIOUS** In 100 people receiving FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, Oxaliplatin),  more than 20 and up to 100 may have: |
| --- |
| * Cholinergic syndrome, which may cause increased sweating, flushed skin, watering eyes, stuffy nose, drooling * Shortness of breath * Infection, possibly in the blood, especially when white blood cell count is low * Bruising, bleeding or internal bleeding which may cause black tarry stools, blood in vomit or urine, or coughing up blood * Anemia which may require a blood transfusion * Severe diarrhea, nausea, vomiting, constipation, loss of appetite, weight loss, belly pain * Sores in mouth which may cause difficulty swallowing * Numbness, pain and tingling of the arms, legs, fingers, and/or toes * Tingling or a loss of feeling in your hands, feet, nose, or tightness in throat or jaw, or difficulty swallowing or breathing which may be made worse by exposure to cold (may occur more than 14 days after administration of the drug) * Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, emptying the bladder (may occur more than 14 days after administration of the drug) * Swelling, redness, or pain at the site of medication injection * Hand-foot syndrome (palmar-plantar erythrodysesthesia) which may cause redness, pain or peeling of palms and soles * Increased risk of sunburn, itching, blisters on the skin, dry skin * Fever, pain, cough * Tiredness, weakness, dizziness * Hair loss |

| **OCCASIONAL, SOME MAY BE SERIOUS** In 100 people receiving FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, Oxaliplatin), from 4 to 20 may have: |
| --- |
| * Chest pain, shortness of breath * Abnormal heartbeat or change in heart rhythm which may cause fainting * Stroke, which may cause paralysis, weakness, headache * Swelling of the body, including the belly, which may cause shortness of breath * Low blood pressure which may cause feeling faint * Confusion * Damage to the lungs which may cause shortness of breath, cough, wheezing * Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat * Blood clot, including in the lung, which may cause swelling, pain, shortness of breath * Bleeding from multiple sites including bleeding of the brain * Liver damage or scarring which may cause yellowing of eyes and skin * Visual loss, visual disturbances, abnormal eye movement, discomfort from light, watering eyes * Hearing loss * Dehydration * Sores in stomach which may cause belly pain * Heartburn, passing gas * Changes in taste, voice, dry mouth * Damage to the muscles which may cause muscle pain, dark red urine * Muscle weakness * Difficulty sleeping * Headache, chills, stuffy nose * Change in skin or nails, rash |

| **RARE, AND SERIOUS** In 100 people receiving FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, Oxaliplatin), 3 or fewer may have: |
| --- |
| * Posterior Reversible Encephalopathy Syndrome which may cause headache, seizure, blindness * Heart attack or heart failure, which may cause shortness of breath, swelling of ankles, and tiredness * Altered mental status, confusion, disorientation, coma, difficulty walking and balancing * Sinusoidal obstructive syndrome (SOS) which may cause damage to the liver, yellowing of the eyes and skin, swelling * Hemolytic uremic syndrome which may cause anemia, kidney problems, tiredness, bruising, swelling, or may require dialysis * Kidney damage which may cause swelling, may require dialysis * Blockage of the bowels which may cause pain, vomiting, constipation * Stevens-Johnson syndrome which may cause severe skin rash with blisters and peeling which can involve the mouth and other parts of the body |