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

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| **COMMON, SOME MAY BE SERIOUS** In 100 people receiving FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, and Oxaliplatin), more than 20 and up to 100 may have: |
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| * Cholingeric syndrome, which may cause increased sweating, flushed skin, watering eyes, stuffy nose, drooling * Cough, shortness of breath * Infection, possibly in the blood, especially when white blood cell count is low * Anemia which may require a blood transfusion * Bruising, bleeding * Severe diarrhea, nausea, vomiting, constipation, loss of appetite, weight loss * Sores in mouth which may cause difficulty swallowing * Swelling and redness at the site of medication injection * 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) * Hand-foot syndrome (palmar-plantar erythrodysesthesia) redness, pain or peeling of palms and soles * Rash, increased risk of sunburn, itching, blisters on the skin, dry skin * Fever, pain * 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: |
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| * Chest pain * Abnormal heartbeat which may cause fainting * Stroke, which may cause paralysis, weakness, headache * Blockage of the airway which may cause shortness of breath, cough, wheezing * Swelling of the body which may cause shortness of breath * Low blood pressure which may cause feeling faint * Altered mental status, confusion, disorientation, intense feelings of joy, difficulty walking and balancing, coma * Scarring of the lungs * Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat * Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain * Internal bleeding which may cause black tarry stool, blood in vomit or urine, or coughing up blood * Blood clot which may cause swelling, pain, shortness of breath * Liver damage which may cause yellowing of eyes and skin * Visual disturbances, abnormal eye movement, discomfort from light, watering eyes * Hearing loss * Sores in stomach which may cause belly pain * Heartburn, passing gas, abdominal swelling * Damage to the muscles which may cause muscle pain, dark red urine * Muscle weakness * Inability to move shoulder or turn head * Dehydration * Difficulty sleeping or drowsiness * Headache, chills * Stuffy nose * Change in skin or nails * Change in taste, voice |

| **RARE, AND SERIOUS** In 100 people receiving FOLFIRINOX (Leucovorin, 5-Fluorouracil, Irinotecan, Oxaliplatin), 3 or fewer may have: |
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| * Heart attack or heart failure, which may cause shortness of breath, swelling of ankles, and tiredness * Brain damage, Posterior Reversible Encephalopathy Syndrome, which may cause headache, seizure, blindness * Kidney damage which may require dialysis * Stevens-Johnson syndrome which may cause severe skin rash with blisters and peeling which can involve the mouth and other parts of the body |