

Abbreviated Package Insert of CRYSVITA Solution for Injection 10 mg/1mL, 20 mg/1mL, or 30 mg/1mL

Composition: Burosumab. **Indication:** Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 yr of age and older. **Dosage & Administration:** Pediatric: BW<10 kg: 1 mg/kg (rounded to the nearest 1 mg), administered q2w. BW>10 kg: starting dose is 0.8 mg/kg (rounded to the nearest 10 mg), administered q2w. The starting dose should be between 10 to 90 mg. Dose may be increased to ~2mg/kg (max 90 mg), administered q2w to achieve normal serum P. Adult: 1 mg/kg (rounded to the nearest 10 mg, max dose: 90 mg), administered q4w. **Contraindications:** Concomitant use with oral phosphate &/or active vit D analogs due to the risk of hyperphosphatemia; serum phosphorus is within/above the normal range for age; severe renal impairment/ESRD due to abnormal mineral metabolism. **Precautions:** Hypersensitivity; hyperphosphatemia & risk of nephrocalcinosis; injection site reactions; Pregnancy & lactation; Pediatric <1 yr of age; Elderly; Renal impairment. **Common adverse reactions:** For pediatric: pyrexia; injection site reactions, cough, vomiting; pain in extremity; headache; tooth abscess; dental caries. For adults: back pain; headache; tooth infection; restless leg syndrome; vitamin D decreased; dizziness; constipation; muscle spasms; increase serum P. **Interaction:** Oral phosphate and active vit D analogs. **P/P:** Injection: 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vial. Approved version of package insert: Jan 2020

Please refer to the full prescribing information before prescribing. Further information is available upon request.