

## **PRESCRIBING INFORMATION**

### **1 Name of the Medicinal Product**

CRYSVITA 10 mg  
CRYSVITA 20 mg  
CRYSVITA 30 mg

Solution for Subcutaneous Injection

### **1.1 Qualitative and Quantitative Composition**

CRYSVITA 10 mg solution for injection Each vial contains 10 mg of burosumab in 1 ml solution.

CRYSVITA 20 mg solution for injection Each vial contains 20 mg of burosumab in 1 ml solution.

CRYSVITA 30 mg solution for injection Each vial contains 30 mg of burosumab in 1 ml solution.

## **2. Therapeutic Indications**

CRYSVITA is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

## **3. DOSAGE AND ADMINISTRATION**

### **3.1 Important Dosage and Administration Information**

Discontinue oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) 1 week prior to initiation of treatment [see *Contraindications (5)*].

Fasting serum phosphorus concentration should be below the reference range for age prior to initiation of treatment [see *Contraindications (5)*].

CRYSVITA is administered by subcutaneous injection and should be administered by a healthcare provider.

The maximum volume of CRYSVITA per injection is 1.5 mL. If multiple injections are required, administer at different injection sites.

### **3.2 Pediatric Patients with X-linked Hypophosphatemia (1 to less than 18 years of age)**

For patients who weigh less than 10 kg, the recommended starting dose is 1 mg/kg of body weight, rounded to the nearest 1 mg, administered every two weeks.

For patients who weigh 10 kg and greater, the recommended starting dose regimen is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.

After initiation of treatment with CRYSVITA, measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is above the lower limit of the reference range for age and below 5 mg/dL, continue treatment with the same dose.

Follow dose adjustment schedule below to maintain serum phosphorus within the reference range for age.