How to use CRYSVITA® (burosumab-twza)

Essential tips for healthcare professionals on preparation, administration, product storage, and handling

Not actual size

CRYSVITA®
burosumab-twza
Injection 10, 20, 30 mg/mL

Please see Important Safety Information on pages 2, 6-8 and click for the full Prescribing Information for CRYSVITA.

Indication

CRYSVITA® (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for:

- The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- The treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

Important Safety Information

CONTRAINDICATIONS

CRYSVITA is contraindicated:

- In concomitant use with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol) due to the risk of hyperphosphatemia.
- When serum phosphorus is within or above the normal range for age.
- In patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism.

WARNINGS AND PRECAUTIONS

Hypersensitivity

- Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients with CRYSVITA. Discontinue CRYSVITA if serious hypersensitivity reactions occur and initiate appropriate medical treatment.

Please see Important Safety Information continued on pages 6-8 and click for the full Prescribing Information for CRYSVITA.

General considerations for subcutaneous injections

CRYSVITA® is supplied[1]

- As a sterile, preservative-free, clear to slightly opalescent and colorless to pale brown-yellow solution for subcutaneous injection

Before injecting CRYSVITA[1]

- Visually inspect CRYSVITA for particulate matter and discoloration prior to administration
- Do not use if the solution is discolored or cloudy or if the solution contains any particles or foreign particulate matter

CRYSVITA is administered[1]

- By subcutaneous injection and should be administered by a healthcare provider

General considerations[1]

- Injection sites should be rotated, with each injection administered at a different anatomic location (upper arms, upper thighs, buttocks, or any quadrant of abdomen) than the previous injection. Do not inject into moles, scars, or areas where the skin is tender, bruised, red, hard, or not intact
- If a given dose on a dosing day requires multiple vials of CRYSVITA, contents from 2 vials can be combined for injection. The maximum volume of CRYSVITA per injection is 1.5 mL
- If multiple injections are required on a given dosing day, administer at different injection sites. Monitor for signs of reactions

Please see Important Safety Information on pages 2, 6-8 and click for the full Prescribing Information for CRYSVITA.

Dosage strengths

How CRYSVITA® is supplied[1]

- CRYSVITA is available as **1 single-dose vial per carton** in the following strengths:

10 mg/mL
(NDC# 42747-102-01)

20 mg/mL
(NDC# 42747-203-01)

30 mg/mL
(NDC# 42747-304-01)

CRYSVITA dosing is based on a patient's weight. Continue to monitor their weight and make any dose adjustments as indicated in the Dosing and Administration Guide.[1]

Missed dose[1]

- If a patient misses a dose, **resume CRYSVITA as soon as possible** at the prescribed dose
- **To avoid missed doses**, treatments may be administered 3 days either side of the scheduled treatment date

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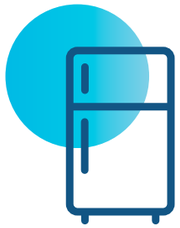
Product storage and handling



How to store CRYSVITA®[1]

CRYSVITA vials must be stored in the original carton until the time of use under refrigerated conditions at 36 °F to 46 °F (2 °C to 8 °C). Keep the CRYSVITA vial in the original carton to protect it from light until the time of use.

How to handle CRYSVITA[1]

- Do not freeze or shake CRYSVITA
- Do not use CRYSVITA beyond the expiration date stamped on the carton
- CRYSVITA vials are single-dose only. Discard any unused product

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Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

Hyperphosphatemia and Risk of Nephrocalcinosis

- Increases in serum phosphorus to above the upper limit of normal may be associated with an increased risk of nephrocalcinosis. For patients already taking CRYSVITA, dose interruption and/or dose reduction may be required based on a patient's serum phosphorus levels.
- Patients with TIO who undergo treatment of the underlying tumor should have dosing interrupted and adjusted to prevent hyperphosphatemia.

Hypercalcemia

- Increases in serum calcium have been reported in patients treated with CRYSVITA. Patients with risk factors such as pre-existing hyperparathyroidism, prolonged immobilization, dehydration, hypervitaminosis D, or renal impairment, are at higher risk of hypercalcemia. Monitor these patients for serum calcium and parathyroid hormone levels before and during CRYSVITA treatment for moderate to severe hypercalcemia. In patients with moderate to severe hypercalcemia, CRYSVITA should not be administered until hypercalcemia is adequately managed.

Injection Site Reactions

- Administration of CRYSVITA may result in local injection site reactions. Discontinue CRYSVITA if severe injection site reactions occur and administer appropriate medical treatment.

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CRYSVITA® burosumab-twza Injection 10, 20, 30 mg/mL

Important Safety Information

ADVERSE REACTIONS

Pediatric Patients

- Adverse reactions reported in 10% or more of CRYSVITA-treated pediatric XLH patients across three studies are: pyrexia (55%, 44%, and 62%), injection site reaction (52%, 67%, and 23%), cough (52%), vomiting (41%, 48%, and 46%), pain in extremity (38%, 46%, and 23%), headache (34% and 73%), tooth abscess (34%, 15%, and 23%), dental caries (31%), diarrhea (24%), vitamin D decreased (24%, 37%, and 15%), toothache (23% and 15%), constipation (17%), myalgia (17%), rash (14% and 27%), dizziness (15%), and nausea (10%).

Adult Patients

- Adverse reactions reported in more than 5% of CRYSVITA-treated adult XLH patients and in at least 2 patients more than placebo in one study are: back pain (15%), headache (13%), tooth infection (13%), restless legs syndrome (12%), vitamin D decreased (12%), dizziness (10%), constipation (9%), muscle spasms (7%), and blood phosphorus increased (6%).
- Spinal stenosis is prevalent in adults with XLH, and spinal cord compression has been reported. It is unknown if CRYSVITA therapy exacerbates spinal stenosis or spinal cord compression.
- Adverse reactions reported in more than 10% of CRYSVITA-treated adult TIO patients in two studies are: tooth abscess (19%), muscle spasms (19%), dizziness (15%), constipation (15%), injection site reaction (15%), rash (15%), and headache (11%).

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USE IN SPECIFIC POPULATIONS

- There are no available data on CRYSVITA use in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Serum phosphorus levels should be monitored throughout pregnancy. Report pregnancies to the Kyowa Kirin, Inc. Adverse Event reporting line at 1-844-768-3544.
- There is no information regarding the presence of CRYSVITA in human milk or the effects of CRYSVITA on milk production or the breastfed infant. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CRYSVITA and any potential adverse effects on the breastfed infant from CRYSVITA or from the underlying maternal condition.

PATIENT COUNSELING INFORMATION

- Advise patients not to use any oral phosphate and/or active vitamin D analog products.
- Instruct patients to contact their physician if hypersensitivity reactions, injection site reactions, and restless legs syndrome induction or worsening of symptoms occur.

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Kyowa Kirin, Inc. at 1-844-768-3544.

For important risk and use information, please click to see the full Prescribing Information for CRYSVITA.

Reference: 1. CRYSVITA (burosumab-twza). US Prescribing Information. Kyowa Kirin, Inc.; August 2025.

KYOWA KIRIN

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