HIGHLIGHTS OF PRESCRIBING INFORMATION
CRYSVITA® (BUROSUMAB)

These highlights do not include all the information needed to use Crysvita safely and effectively. See full prescribing information for Crysvita. Crysvita® (burosumab) injection, for subcutaneous use initial U.S. Approval: 2018

INDICATIONS AND USAGE:

CRYSVITA is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

DOSAGE AND ADMINISTRATION:

For subcutaneous use only.

• **Pediatric XLH:** 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. Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.

• **Adult XLH:** Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks.

DOSAGE FORMS AND STRENGTHS:

Injection: 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vial

CONTRAINDICATIONS:

- Do not use CRYSVITA with oral phosphate and active vitamin D analogs.
- Do not initiate CRYSVITA if serum phosphorus is within or above the normal range for age.
- CRYSVITA is contraindicated in patients with severe renal impairment or end stage renal disease.

WARNINGS AND PRECAUTIONS:

• **Hypersensitivity**: Discontinue CRYSVITA if serious hypersensitivity reactions occur and initiate appropriate medical treatment.

• **Hyperphosphatemia and 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.

• **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.

ADVERSE REACTIONS:

Most common adverse reactions (≥25%) in pediatric XLH patients are: headache, injection site reaction, vomiting, pyrexia, pain in extremity, vitamin D decreased.

Most common adverse reactions (≥5%) and in at least 2 patients more than placebo) in adult XLH patients are: back pain, headache, tooth infection, restless leg syndrome, vitamin D decreased, dizziness, constipation, blood phosphorus increased.

PI Date of Preparation: September 2018

Dispension Mode: POM

Marketing Authorisation: Kyowa Kirin Inc. USA

Adverse events should be reported to drugsafetygcc@kyowakirin.com or by phone: 00971551874456.

Full Prescribing Information is available upon request.

For reporting any side effects or safety information, please contact us directly via:
e-mail: drugsafetygcc@kyowakirin.com Hotline: +971 55 187 4456 | Landline: +971 4 581 3700 | Fax: +971 4 581 3776

To report any side effect(s):

• Saudi Arabia: - The National Pharmacovigilance and Drug Safety Centre (NPC):
Fax: +966-11-205-7662. Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340
Toll free phone: 8002490000 - E-mail: npc.drug@sfda.gov.sa - Website: https://ade.sfda.gov.sa/
• Other GCC States: - Please contact the relevant competent authority.