FOR PEDIATRIC PATIENTS


*Actor portrayal.

LEARN ABOUT ^{Pr}CRYSVITA®

(burosumab injection)

Your child's XLH treatment guide

This guide is solely intended for parents and caregivers of Canadian patients who have been prescribed CRYSVITA.

Understanding your child's X-linked hypophosphatemia (XLH) treatment with CRYSVITA

Learn how CRYSVITA works, what to expect at your child's treatment appointment, and more.

*Actor portrayal.

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What is XLH?

X-linked hypophosphatemia (XLH) is a genetic disease. People with XLH have higher levels of a hormone called **fibroblast growth factor 23** (FGF23). FGF23 lowers the amount of phosphate in the blood. The low level of phosphate may lead to bones that cannot grow and harden properly.

The content below provides information on XLH and may not reflect benefits of CRYSVITA.

What are the symptoms of XLH in children?

In children, symptoms of XLH may include:

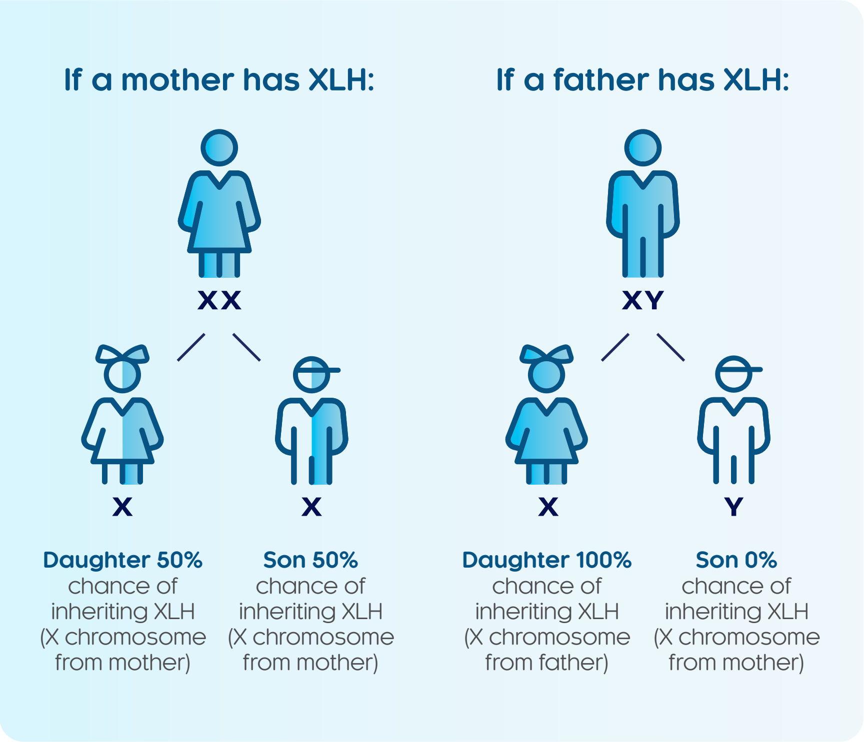
- Rickets
- Bowed legs or knock knees
- Tooth abscesses
- Waddling gait (abnormal pattern of walking or running)
- Delayed growth rate

*Actor portrayal.

Who gets XLH?

In most cases, XLH is an inherited disease, which means parents pass XLH down to their children. If you have XLH, other people in your extended family may have it, too.

X-linked means that the gene affected is on the **X chromosome**. Females have two X chromosomes, while males have one X chromosome and one Y chromosome.



If a mother has XLH:

Daughter 50% chance of inheriting XLH (X chromosome from mother)

Son 50% chance of inheriting XLH (X chromosome from mother)

If a father has XLH:

Daughter 100% chance of inheriting XLH (X chromosome from father)

Son 0% chance of inheriting XLH (X chromosome from mother)

In about **20%** of cases, a person develops XLH without any family history.

XLH is a rare disorder, affecting up to 1 in 20,000 people.

About CRYSVITA

What is CRYSVITA?

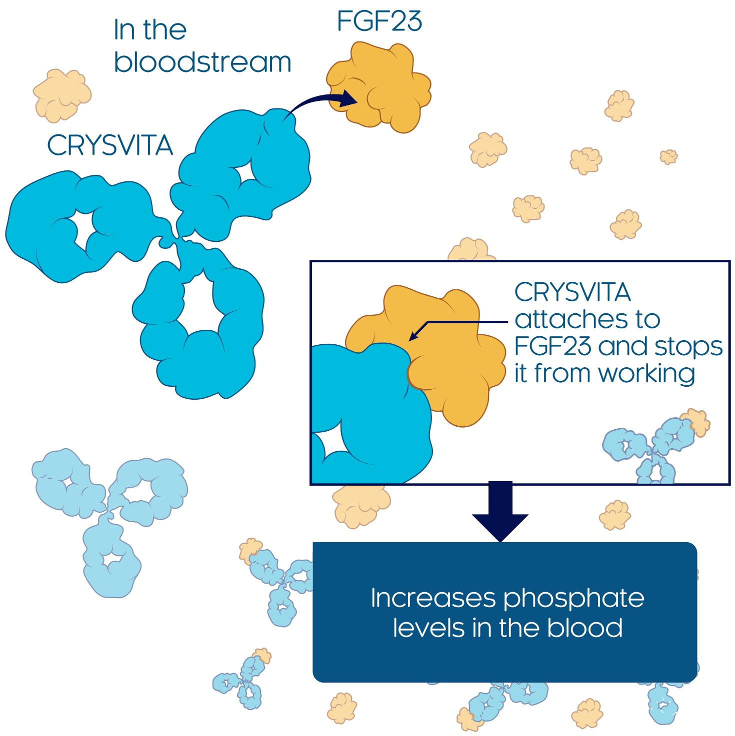
CRYSVITA contains the active substance **burosumab**. This is a type of medicine called a **human monoclonal antibody**.

Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body.

CRYSVITA is used to treat **X-linked hypophosphatemia** (XLH). It is used in children 6 months of age and older and adults.

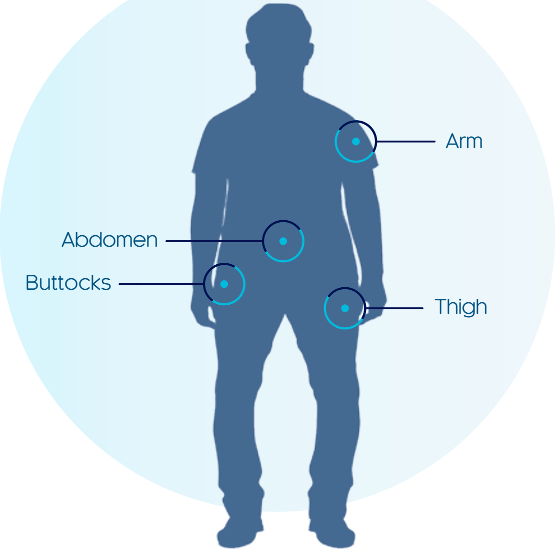
How does CRYSVITA work?

CRYSVITA attaches to FGF23 in the blood, which stops FGF23 from working and increases phosphate levels in the blood so that normal levels of phosphate can be achieved.



How will my child be given CRYSVITA?

A trained healthcare professional should give your child CRYSVITA as an injection under the skin, in the arm, abdomen (stomach area), buttocks or thigh.



The amount of CRYSVITA your child is given (called the dose) is based on their body weight. Your child's healthcare professional will determine the right dose for them.

In children, CRYSVITA is given **every 2 weeks**.

It's important to keep a close eye on your child during their CRYSVITA treatment. Tell your child's healthcare professional if they experience the following serious side effects:

- **Skin reactions** (only if severe). *These are very common.*
- **Dizziness** (only if severe). *This is very common.*
- **Allergic reactions** shortly after being given CRYSVITA (in <u>all cases</u>). Symptoms: rash and itching all over the body; severe swelling of eyelids, mouth, or lips; shortness of breath; rapid heartbeat; and sweating. *These are rare.*

If your child experiences any side effects not listed here, or that interferes with their daily activities, talk to their doctor.

Before starting CRYSVITA

Your child should not take CRYSVITA if they:

- Are allergic to burosumab or any of the other ingredients in this medication
- Are taking any phosphate or active vitamin D
- Already have a high level of phosphate in their blood (called hyperphosphatemia)
- Have severe kidney disease or kidney failure

To help your child avoid side effects and ensure proper use of CRYSVITA, talk to their doctor before they start CRYSVITA. This includes any health conditions or problems they may have, including if they are:

- Taking phosphates or active vitamin D, such as those with the active ingredient calcitriol or alfacalcidol. There are some non-active vitamin D supplements they can use, and your child's doctor will advise which ones these are.

Tell your child's doctor about all the medicines they take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines. Studies to test how CRYSVITA interacts with other medicines have not been done.

Important safety information about CRYSVITA

Other warnings to know about:

Skin reactions

Your child may get skin reactions where they receive their injection. If they are severe, contact your child's healthcare professional right away.

Children with XLH under 6 months

CRYSVITA should not be given to children with XLH under 6 months of age because the safety and effects of the medicine have not been studied in this age group.

Possible side effects

Like all medicines, CRYSVITA can cause side effects, although not everybody gets them. Side effects in children may include:

- Tooth abscess (infection)
- Toothache
- Cough
- Headache
- Vomiting
- Nausea
- Diarrhea
- Constipation
- Tooth decay or cavities
- Rash
- Pain in muscles (myalgia) and hands and feet
- Reactions where the injection was given, which may include:
  - Redness or rash
  - Pain or itching
  - Swelling
  - Bleeding or bruising
- Fever
- Low vitamin D
- Dizziness

If your child experiences any side effects not listed here, or that interfere with their daily activities, talk to their doctor.

Getting started with CRYSVITA

What to expect at your child's treatment appointment:

We understand that having your child start on new medication may feel challenging. **Remember: your child's healthcare team is there to support you both.** If you have any questions, don't hesitate to ask them.

Their healthcare professional may take blood and urine samples to measure their phosphate levels. This is done to reduce the risk of hyperphosphatemia (too much phosphate in the blood).

These tests allow your child's healthcare professional to know if your child is getting the right dose of CRYSVITA and adjust it, if needed.

Questions the doctor or nurse may ask you:

- Is your child currently taking any medications?
- Does your child have any allergies?
- Does your child have any kidney problems?

Your answers to these questions will help inform your child's CRYSVITA treatment plan.

A healthcare professional should administer CRYSVITA.

If you miss an appointment, talk to your child's healthcare professional right away. The missed dose should be given as soon as possible.

After your child's injection, they may be monitored for a short period of time.

After your child's appointment

If you have questions or concerns, reach out to your child's doctor. Be sure to keep your appointments for your child's scheduled CRYSVITA injections. Writing them down in a calendar or scheduling them in your phone may help you remember.

If your child is stressed by the thought of needle injections, consider these tips.

1. Before the injection, have a **conversation** about why they are receiving CRYSVITA and what they may feel during the injection. Consider using words like "poking" or "pressure" instead of "hurt" or "sting". Smile and speak in a calm and positive tone.
2. Various topical numbing creams/gels are available over the counter at the pharmacy. It is recommended to apply 30-60 minutes before an injection. Talk to your child's healthcare professional about whether this is an appropriate option and which ones may be suitable for your child.
3. Take a deep **breath** together. Deep breathing can help them relax, and it can also act as a distraction.
4. **Distract** your child – distractions (e.g., music, toys, electronics, talking) may help divert their attention from the injection.

Kyowa KIRIN cares
ACCESS • ASSISTANCE • UNDERSTANDING
SUPPORT PROGRAM

Support throughout your child's CRYSVITA treatment journey

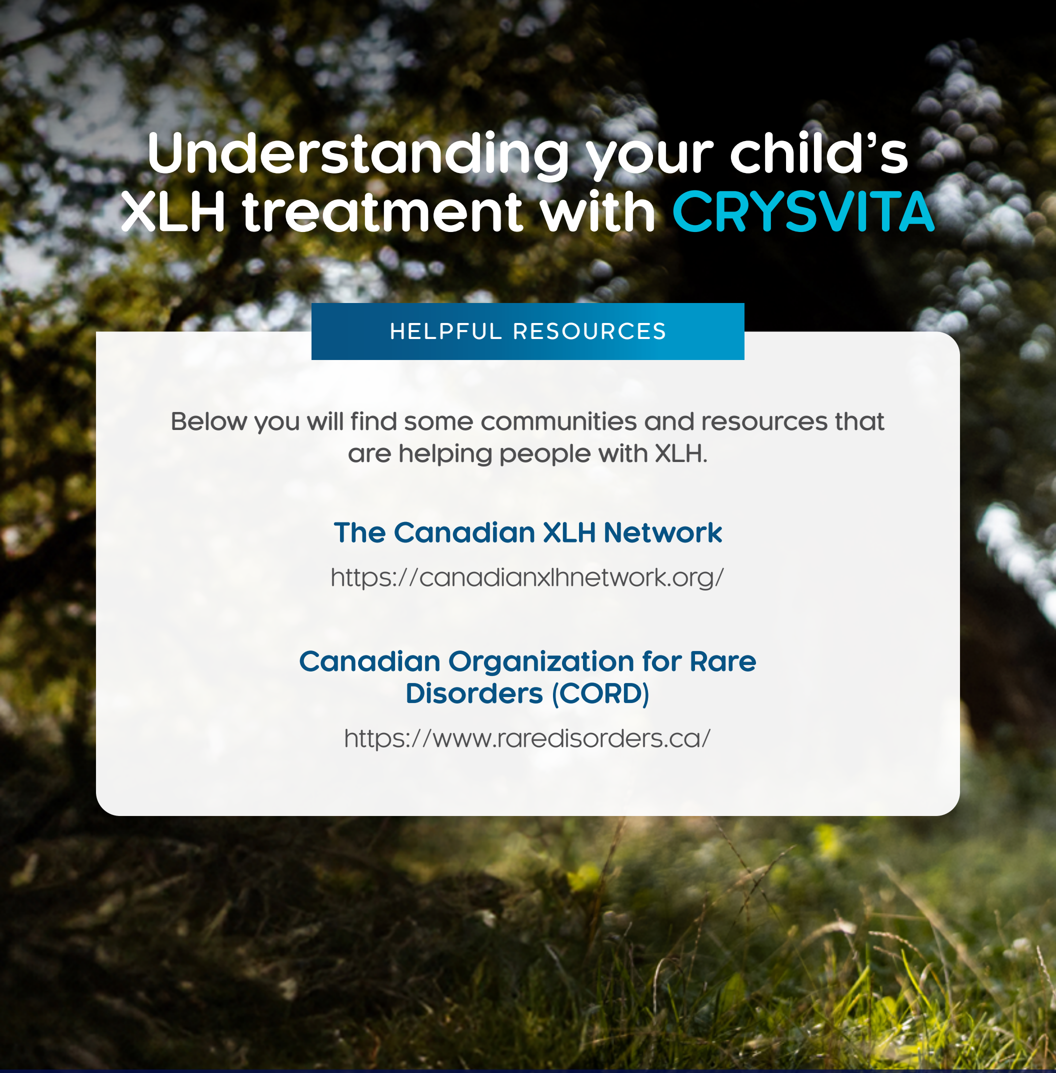
Kyowa Kirin is committed to patients with rare diseases, which is why we created the Kyowa Kirin Cares™ Patient Support Program—a suite of services designed to help you along your CRYSVITA treatment journey.

Our **Nurse Case Managers** are experienced professionals who are passionate about supporting you at every step. They can help you:

- Learn about CRYSVITA therapy
- Understand your insurance coverage
- Determine your eligibility for financial assistance
- Coordinate the delivery of your CRYSVITA and injection supplies
- Schedule your child's CRYSVITA injections

Talk to your child's doctor about enrolling into the Kyowa Kirin Cares™ Patient Support Program.

If you have any questions, call us at 1-833-KYOWA-CA (1-833-596-9222).



Understanding your child's XLH treatment with CRYSVITA

HELPFUL RESOURCES

Below you will find some communities and resources that are helping people with XLH.

The Canadian XLH Network

https://canadianxlhnetwork.org/

Canadian Organization for Rare Disorders (CORD)

https://www.raredisorders.ca/

PrCRYSVITA®
burosumab injection
Solution for Subcutaneous Injection
10, 20, 30 mg/mL

KYOWA KIRIN

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REVIEWED BY PAAB