

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using CRYSVITA?

CRYSVITA contains the active ingredient burosumab. CRYSVITA is used to treat X-linked hypophosphataemia (XLH) and tumour-induced osteomalacia (TIO).

For more information, see Section [1. Why am I using CRYSVITA?](#) in the full CMI.

2. What should I know before I use CRYSVITA?

Do not use if:

- you have ever had an allergic reaction to CRYSVITA or any of the ingredients listed at the end of the CMI.
- you are taking any phosphate supplements or certain vitamin D supplements (that contain so called active vitamin D, e.g. calcitriol)
- you already have a normal to high level of phosphate in your blood
- you have severe kidney disease or kidney failure.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CRYSVITA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may affect how CRYSVITA works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CRYSVITA?

- CRYSVITA should be given by injection by a trained healthcare provider.
- The dose is based on your body weight. Your doctor will work out the right dose for you.

More instructions can be found in Section [4. How do I use CRYSVITA?](#) in the full CMI.

5. What should I know while using CRYSVITA?

Things you should do	<ul style="list-style-type: none"> • Stop taking CRYSVITA and tell your doctor straight away if you have any of the following side effects, as they could be signs of an allergic reaction: rash and itching all over the body, severe swelling of eyelids, mouth, or lips (angioedema), shortness of breath, rapid heartbeat, sweating. • You may get skin reactions where the injection is given. If these reactions are severe, tell your doctor. • Remind any doctor, dentist, or pharmacist you visit that you are using CRYSVITA.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how CRYSVITA affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Store in a refrigerator (2°C to 8°C). Do not freeze. • Keep the vial in the outer carton in order to protect from light.

For more information, see Section [5. What should I know while using CRYSVITA?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

CRYSVITA®

Active ingredient: *burosumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CRYSVITA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CRYSVITA.**

Where to find information in this leaflet:

- [1. Why am I using CRYSVITA?](#)
- [2. What should I know before I use CRYSVITA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CRYSVITA?](#)
- [5. What should I know while using CRYSVITA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CRYSVITA?

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

CRYSVITA is used to treat X-linked hypophosphataemia (XLH). It is used in adults and children of 1 year and older.

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 may not harden properly and, in children and adolescents, cannot grow properly
 - result in pain and stiffness in bones and joints.

CRYSVITA is used to treat tumour-induced osteomalacia (TIO) where the tumour causing this condition cannot be successfully removed by surgery, or the tumour cannot be found. It is used in children and adolescents aged 1 to 17 years and in adults.

- People with TIO have higher levels of a hormone called FGF23 produced by certain types of tumours.
- FGF23 lowers the amount of phosphate in the blood.
- The low level of phosphate may lead to softening of the bones, muscle weakness, tiredness, bone pain and fractures.

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

2. What should I know before I use CRYSVITA?

Warnings

Do not use CRYSVITA if:

- you are allergic to burosumab, or any of the ingredients listed at the end of this leaflet.
- you are taking any phosphate supplements or certain vitamin D supplements (that contain so called active vitamin D, e.g. calcitriol)
- you already have a normal to high level of phosphate in your blood
- you have severe kidney disease or kidney failure.

Always check the ingredients to make sure you can use this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Burosumab is not recommended for use during pregnancy. Check with your doctor if you are pregnant or intend to become pregnant.

If you could get pregnant, you must use an effective method of contraception (birth control) while using CRYSVITA and for at least 14 weeks after your last dose. You should discuss this with your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if CRYSVITA will affect the baby.

Tests and checks

Your doctor will check the phosphate and calcium levels in your blood and urine and may also do a renal ultrasound before and during your treatment in order to reduce the risk of hyperphosphataemia (too much phosphate in the blood), hypercalcaemia (too much calcium in the blood) and ectopic mineralisation (a build-up of calcium in tissues such as the kidneys). Your serum parathyroid hormone level will

also be checked before and during your treatment in order to reduce the risk of hyperparathyroidism (too much parathyroid hormone in the blood).

Children under 1 year

The safety and effects of the medicine have not been studied in children under 1 year of age.

CRYSVITA contains sorbitol

This medicine contains 45.91 mg of sorbitol in each vial which is equivalent to 45.91 mg/ml.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Before using CRYSVITA, talk to your doctor if you:

- are taking a type of medicine known as a calcimimetic. Your doctor may monitor your calcium levels more closely.
- have problems with your parathyroid glands.
- are a patient with TIO and you are about to receive treatment of the underlying tumour (i.e. radiation therapy or surgical removal). In this case, treatment with CRYSVITA will not be started until after the treatment of the underlying tumour and if the serum phosphate levels are low.

Do not take CRYSVITA and tell your doctor if you are taking:

- phosphate supplements
- certain vitamin D supplements (that contain so called active vitamin D, e.g. calcitriol). There are some vitamin D supplements you can continue or start to use and your doctor will advise which ones these are.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CRYSVITA.

4. How do I use CRYSVITA?

CRYSVITA should be given by injection under the skin in the arm, abdomen, buttock, or thigh by a trained healthcare provider.

How much to use

Dose for XLH and TIO

- The dose is based on your body weight. Your doctor will work out the right dose for you.
- CRYSVITA will be injected

- every two weeks in children 1 year of age and older
- every four weeks in adults.

- Your doctor will perform checks to make sure that you are getting the right dose and may change your dose if needed.

Maximum dose for XLH patients

- The maximum dose you will be given is 90 mg.

Maximum dose for TIO patients

- The maximum dose you will be given for the treatment of TIO:
 - for children aged 1 to 12, is 90 mg
 - for adolescents aged 13 to 17 and for adults, is 180 mg.

Patients with TIO

If you are a patient with TIO who requires treatment of the underlying tumour (i.e. radiation therapy or surgical removal), treatment with CRYSVITA will be stopped by your doctor. After treatment of the tumour is completed, your doctor will perform checks of your phosphate levels and restart treatment with CRYSVITA if serum phosphate levels are low.

If you forget to use CRYSVITA

If a dose is missed, talk to your doctor straight away. The missed dose should be given as soon as possible and your doctor will re-arrange future doses accordingly.

If you use too much CRYSVITA

If you think that you have been given too much CRYSVITA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using CRYSVITA?

Things you should do

Allergic reactions

Call your doctor straight away if you have any of the following side effects, as they could be signs of an allergic reaction:

- rash and itching all over the body
- severe swelling of eyelids, mouth, or lips (angio-oedema)
- shortness of breath
- rapid heartbeat

- sweating.

Do not take CRYSVITA if any of the above apply to you. If you are not sure, talk to your doctor before using CRYSVITA.

Skin reactions

You may get skin reactions where the injection is given, see section [6. Are there any side effects?](#) for more information. If these reactions are severe, tell your doctor.

Remind any doctor, dentist, or pharmacist you visit that you are using CRYSVITA.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CRYSVITA affects you.

It is possible that CRYSVITA could cause dizziness and affect you being able to ride a bike, use any tools or machines or to drive. If you think you are affected, do not ride a bike, use any tools or machines or drive, and tell your doctor.

Looking after your medicine

- Do not use CRYSVITA after the expiry date which is stated on the carton and label.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects in children with XLH

Side effects in children	What to do
<p>Very common (may affect more than 1 in 10 children)</p> <ul style="list-style-type: none"> • Tooth abscess (infection) • Cough • Headache • Vomiting • Nausea • Diarrhoea • Constipation • Tooth decay or cavities • Rash • Pain in muscles (myalgia) and hands and feet • Reactions where the injection was given, which may include: <ul style="list-style-type: none"> – redness or rash – pain or itching – swelling – bleeding or bruising <p>These injection site reactions are usually mild and occur within a day after the injection and usually get better in around 1 to 3 days.</p> • Fever <p>Common (may affect up to 1 in 10 children)</p> <ul style="list-style-type: none"> • Dizziness • Hives • Increased parathyroid hormone in your blood <p>Uncommon (may affect up to 1 in 100 children):</p> <ul style="list-style-type: none"> • High levels of calcium in your blood 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects in adults with XLH

Side effects in adults	What to do
<p>Very common (may affect more than 1 in 10 adults)</p> <ul style="list-style-type: none"> • Tooth abscess (infection) • Headache • Dizziness • Restless legs syndrome (irresistible urge to move your legs to stop uncomfortable, painful or odd sensations in the legs especially prior to sleep or at night time) • Pain in back • Muscle spasm • Reactions where the injection was given, which may include: <ul style="list-style-type: none"> – redness or rash – pain or itching – swelling – bleeding or bruising <p>These injection site reactions are usually mild and occur within a day after the injection and usually get better in around 1 to 3 days.</p> <p>Common (may affect up to 1 in 10 adults)</p> <ul style="list-style-type: none"> • Increased or high levels of parathyroid hormone in your blood • High level of calcium in your urine • Constipation • Hives 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Some side effects such as low vitamin D levels or increased phosphate levels can only be found when your doctor does tests to check your progress.

Side effects in adults with TIO

Side effects in adults	What to do
<p>Very common (may affect more than 1 in 10 adults)</p> <ul style="list-style-type: none"> • Tooth abscess (infection) • Headache • Dizziness • Constipation • Rash • Muscle spasms • Reactions where the injection was given, which may include pain or swelling <p>Common (may affect up to 1 in 10 adults)</p> <ul style="list-style-type: none"> • High level of calcium in your blood • Restless legs syndrome • Low vitamin D in your blood • Increased phosphate in your blood • Increased or high levels of parathyroid hormone in your blood 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CRYSVITA contains

Active ingredient (main ingredient)	burosumab
Other ingredients (inactive ingredients)	L-histidine D-sorbitol polysorbate 80 L-methionine 10%, hydrochloric acid water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What CRYSVITA looks like

CRYSVITA comes as a clear to slightly opalescent, colourless to pale yellow/brown solution for injection in a small glass vial. Each pack contains 1 vial.

AUST R 340793 (10 mg/mL)

AUST R 340796 (20 mg/mL)

AUST R 340797 (30 mg/mL)

Who distributes CRYSVITA

Kyowa Kirin Australia Pty Ltd
Level 7
68 York Street
Sydney, NSW 2000

www.kyowakirin.com/australia

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