



STARTING ON CRYSVITA[®]

A guide for PARENTS AND CARERS



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A vibrant sunflower field under a bright, sunny sky. The sunflowers are in various stages of bloom, with bright yellow petals and dark brown centers. The background is a soft, out-of-focus field of similar flowers, creating a warm and positive atmosphere.

WELCOME

This guide supports parents and carers of children who have been prescribed Crysvisa (burosumab) to treat X-linked hypophosphataemia (XLH).

XLH is a genetic disease that is mostly passed down in families but can also happen spontaneously. It is due to changes in the PHEX gene on the X chromosome. Children with XLH have too much of a hormone called FGF23. This acts on the kidney and increases the excretion of phosphate, leading to a reduction of phosphate in the blood. Phosphate is needed for healthy bone growth.

While XLH is a lifelong condition with symptoms that vary from person to person, we believe every child with XLH should have the chance to have their condition managed as effectively as possible. Crysvisa has been developed with that goal in mind.

In this guide you will find information about getting your child started on Crysvisa, as well as tips for supporting them over the months to follow. We've included ways to make injections easier, ideas for confidence-boosting goals plus some helpful messages to share with your child if they need reassurance. Finally, we've added a Q&A section, providing expert answers to your most likely questions.

Please note this guide is not a substitute for medical advice. It's important to talk to your child's doctor if you have any concerns or questions about Crysvisa or XLH.

GETTING STARTED

Your child's experience of having Crysvida will start with a period of preparation and adjustment that is personal to them. Here is what to expect



Before your child starts on Crysvida the doctor will make sure it is okay for treatment to begin. They will:

- ✓ Consider your child's medical history.
- ✓ Review your child's symptoms of XLH. This may include some investigations, for example an X-ray of their bones, an ultrasound scan of their kidneys, a urine sample and a blood test to check their phosphate and vitamin D levels. The results will give the doctor what is called a 'baseline' against which they can measure how your child's XLH responds to the new medicine.
- ✓ For older teens, a pregnancy test and contraception may be discussed. This is because it isn't yet known what effect Crysvida may have on a developing baby.

If you have been giving your child phosphate and activated vitamin D at home, the doctor will ask you to stop giving these one week before your child's first injection. They should not take them at the same time as Crysvida.

GETTING THE RIGHT DOSE

For Crysvida to work at its best, it is important to get the dose right for your child. The exact dose will depend on your child's weight, as well as the level of phosphate in their blood.

“Your doctor will ask you to stop giving your child phosphate and activated vitamin D one week before your child's first injection.”

Your child will have a blood test every four weeks at first, so that the doctor can check their phosphate levels and determine if they need more or less Crysvida.

Getting the right dose will be an ongoing process of monitoring and adjustment as your child grows. It happens for all children and is not a cause for concern. If you, or your child, have any questions or concerns, talk to the doctor or nurse. They will be able to explain any changes to the dose and reassure you.

SIDE EFFECTS

As with any medicine, Crysvida may cause side effects. Some children may experience side effects which are mostly mild or moderate in intensity. These side effects usually resolve by themselves.

Common side effects are:

- Skin at the injection site becoming red, itchy or slightly swollen. This generally lasts one to three days and goes away by itself.
- Cough
- Headache
- Fever
- Pain in extremity
- Vomiting
- Tooth abscess .

If you are concerned about potential side effects ask your doctor or nurse, who will be able to explain them in more detail.

If your child experiences any side effects after having their Crysvida injection, tell your doctor or nurse and they will be able to advise accordingly.

You may want to keep a diary or take photos of any mild side effects to share with the doctor or nurse. It also forms a record for you to refer back to in future. ■

CRYSVITA IS A NEW TYPE OF MEDICINE FOR XLH

Your child may already take medicine for their XLH. This is likely to be in liquid or tablet form and taken several times each day. It works by topping up the levels of phosphate in your child's body. Crysvida is a new medicine, which works in a different way to this:

- It is given every two weeks
- It may be given at hospital at first
- It is given by injection
- It contains molecules called antibodies which attach themselves to a hormone called FGF23 in your child's blood, slowing it down. This causes your child's body to hold on to more phosphate, which is needed for strong bones.
- As bones get stronger, joint and bone pain can reduce.



SUPPORTING YOUR CHILD

Your child's regular XLH healthcare team will support them, and you, while adjusting to your child's new medicine. It will include your child's doctor and nurses, and possibly other specialists, such as a physiotherapist.

At the centre of this team is the most important person – your child. It's important to help them understand about Crysvida and encourage them to share how they feel. Involving children from the start can help them grow more confident about looking after their health when they get older.

WHAT HAPPENS NEXT

Once your child is settled on Crysvida, the medical team will work together to ensure the best possible experience for your child continues



It may take up to 12 weeks for your medical team to settle on the dose for your child. During this period & afterwards your child will receive 2 weekly injections of Crysvida. After this, fewer tests and checks may be necessary.

Depending on where you live and the nature of your child's XLH, their managing doctor will determine the best health care facility for them to continue having their injections. There is no need to worry if you are asked to take your child to hospital for their injection.

The visit to the clinic for the injection is a good time to share any questions or concerns that you or your child may have.

SUPPORTING YOUR CHILD WITH INJECTIONS

Some children may feel nervous about having an injection. Generally, these feelings fade over time, as injections become more familiar to them.

It's a good idea to encourage your child to talk about how they feel. If they are finding the injection difficult, share this with the nurse. The nurse will have given many injections to children and will know several ways to help.

The nurse may use ice, a numbing cream or a special buzzing device, to de-sensitise the skin before the injection. They can provide distraction aids or help your child with calming breathing exercises or conversation, for example.

If your child continues to feel very anxious about the injection, the nurse may refer them for more support if this is available where you live.

Remember to tell the doctor or nurse if your child experiences any side effects after their injection, even if it occurs some days after.

MONITORING IS STILL IMPORTANT BUT WILL HAPPEN LESS OFTEN

The doctor will continue doing checks to make sure that Crysvida is doing its job.

The kind of tests the doctor will do throughout the course of your child's treatment will be less frequent but are just like those at the beginning. These include:

- ✓ Measuring weight and height
- ✓ Blood and urine tests to check phosphate levels
- ✓ X-rays to check bone health, growth and shape
- ✓ Ultrasound scans to check the kidneys are healthy.

Don't worry if the doctor chooses to do more, or fewer, tests. Every child's monitoring requirement depends on their personal health needs.

SEEING RESULTS

Understandably, your child will want to see and feel the benefits of their new medicine. As their parent or carer, you will want to see positive changes too. As every child's symptoms of XLH are different, your child's doctor should talk to you about your child's progress, and when you may hope to see results.

IF YOUR CHILD WANTS TO STOP TAKING CRYSVITA

There may be times when your child wants to stop having Crysvida. They

may say they 'feel better now' or tire of seeing doctors and nurses. Many children with long-term conditions feel this way about treatment at times, especially teenagers.

It can be difficult for parents and carers to know what to say when their child or teen wants to stop treatment, but their doctor advises that it continue.

Below are some helpful messages you might wish to share with your child. ■

HELPFUL MESSAGES YOU MAY SHARE WITH YOUR CHILD

If your child says 'I'm better now'

It's positive that they feel better, and as XLH is a lifelong condition, you want that good feeling to continue, by following the treatment plan prescribed by the doctor.

If your child feels despondent

Remember that Crysvida takes time to bring results, and your child has done so well to get so far.

If your child feels worried

Encourage them to share their worries with you or their nurse or doctor.



SETTING ACHIEVABLE GOALS

To help your child feel positive, it may help to have smaller goals which make sense in their everyday life. These can be worked towards together and celebrated no matter how small the changes.

Ideas include:

- Feeling a little less pain each day
- Having more energy for fun activities
- Walking a little faster



Q&A

Q: IS IT SAFE FOR MY CHILD TO TAKE CRYSVITA?

A: Crysvida has been approved for use in children over the age of one by Australia's Therapeutic Goods Administration (TGA).

This approval was granted after clinical trials with children over a period of years, to test its safety and efficacy.

During the trials, some children experienced side effects, as can happen with any medicine.

If you have any questions about the safety and monitoring of Crysvida, or side effects, talk to your child's doctor or nurse.

Remember to tell the doctor or nurse if your child experiences any side effects after their injection, even if it occurs some days after.

Q: HOW MIGHT MY CHILD FEEL ABOUT TAKING CRYSVITA?

A: Children respond differently to starting a new medicine. Some may feel positive about the change while others may feel nervous, or worried about the injection.

Talking regularly with your child will give them a chance to share how they feel and what symptoms they have. For younger children, words can be difficult but pictures can help.

The nurse will have ideas about how to help your child share how they feel.

Q: HOW LONG WILL MY CHILD NEED TO HAVE CRYSVITA FOR?

A: XLH is a lifelong condition and, to that end, Crysvida has been approved for use in children and adults by the TGA. Your child will be monitored by their doctor, who will discuss with you and your child how long treatment should continue for.

Q: CAN MY CHILD TAKE TABLETS INSTEAD?

A: No. Crysvida can only be given by injection under the skin. It is not available in tablet form.

Q: WHAT HAPPENS IF WE MISS AN INJECTION?

A: It is important that your child has their Crysvida injection on the prescribed day, but the doctor will understand that this may not always be possible for you.

If your child misses an injection the next injection should happen as soon as possible and within 3 days of the scheduled day. Your child should then be given their next dose as normal.

You should always let the nurse know in advance if you think you may miss an injection, for example to go on holiday. It may be that your doctor might be able to find a solution to allow your child's injections to continue whilst away.

Occasionally the doctor may decide, based on test results, that your child should miss an injection or have two



injections. This is part of getting the dose right, based on your child's needs, and is not a cause for worry.

Q: CAN MY CHILD HAVE THEIR INJECTION AT SCHOOL?

A: Crysvida should be administered by a healthcare provider in a healthcare setting.

Q: WHAT IF MY CHILD IS ILL ON INJECTION DAY?

A: If your child is ill on injection day, contact their doctor or nurse who will advise whether the injection can still go ahead.

Q: WHAT SHOULD I DO IF MY CHILD HAS A SIDE EFFECT?

A: Before your child starts having Crysvida their doctor will explain the possible side



“ You should always let the nurse know in advance if you need to miss an injection, for example to go on holiday. ”





effects and what to look out for. They will advise which side effects can be managed at home and which require further advice or urgent medical attention.

If you are ever in doubt about symptoms or side effects, ask the doctor or nurse. In an emergency situation, always seek urgent medical care.

Q: SHOULD MY CHILD CARRY ON TAKING ACTIVATED VITAMIN D AND PHOSPHATE?

A: No. Both should be stopped one week before starting their new medicine. The doctor will advise whether other supplements are needed.

IS THERE ANY INTERACTION WITH OTHER MEDICINES?

Tell the doctor or nurse if your child is taking, has recently taken or might take, any other medicines, including homeopathic, herbal and natural remedies.

Q: ARE THERE ANY FOODS MY CHILD SHOULD AVOID?

A: No. A normal diet is possible when taking Crysvida. There is no longer any issue with dairy foods, as with medication that may have been taken previously.

Q: IS THERE ANYTHING MY CHILD CAN'T DO?

A: You may wish to be cautious about some physical activities shortly after your child has their Crysvida injection. This is because in some cases children could

experience dizziness after their injection.

Remember to tell the doctor or nurse if your child experiences any side effects after their injection, even if it occurs some days after.

Q: WHO NEEDS TO KNOW ABOUT MY CHILD'S NEW MEDICINE?

A: You may wish to consider telling others responsible for your child's care:

- Your child's school or place of care. This may help with planning absences and spotting symptoms and side effects. It's a good idea to share a list of possible side effects with them.
- The immunisation nurse. Tell them before immunisations take place.
- Your child's dentist. They can look out for changes in your child's teeth that may be related to XLH.

HORMONES, PUBERTY AND FERTILITY

It is not yet known if or how Crysvida could affect hormones, puberty and fertility for girls or boys. Talk to the doctor or nurse if you have any questions or concerns.

PREGNANCY

It is not yet understood if or how Crysvida could affect conception or growth of a developing baby. Therefore, highly effective contraception is recommended for girls who have started their periods. Talk to the doctor or nurse if you have any questions or concerns. ■

RESOURCES

Here are the details of some organisations that might be of help to you throughout your XLH journey.

XLH AUSTRALIA INCORPORATED

A patient support and advocacy group for people living with X-Linked Hypophosphatemia (XLH)

<https://xlhaustralia.com/>

XLH ALLIANCE

An international alliance of patient groups for individuals affected by XLH

<https://xlhalliance.org/>

XLH NETWORK

A worldwide patient support organisation for people living and dealing with XLH

<http://xlhnetwork.org/>

RARE VOICES AUSTRALIA (RVA)

RVA is the national peak body for Australians living with a rare disease.

<https://rarevoices.org.au/>

GENETIC ALLIANCE AUSTRALIA

Genetic Alliance was formed in 1988 to provide peer support and information for individuals and families affected by a rare genetic conditions and rare disease.

<https://www.geneticalliance.org.au/>

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.



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▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.¹

1. Australian Product Information for Crysvita[®] (burosumab) approved Sept 2021. Available at: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02101-1&d=20220917172310101> Last accessed June 2023.

Please consult with your doctor for any questions relating to XLH or its management. Refer to the [Consumer Medicine Information](https://www.kyowakirin.com/australia/our_medicines/doc/crysvita_consumer_medicine_information_leaflet.pdf) (https://www.kyowakirin.com/australia/our_medicines/doc/crysvita_consumer_medicine_information_leaflet.pdf) for more information.

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