

Consumer Medicine Information

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?
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6. Are there any side effects?
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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.

X-Linked Hypophosphataemia (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 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.

Women of childbearing potential who take CRYSVITA should discuss the use of contraception with their 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 during your treatment in order to reduce the risk of hyperphosphataemia (too much phosphate 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 from time to time.

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

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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. Caution is advised when using a combination of a calcimimetic medicine and CRYSVITA.

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.