

HOLOXAN

Ifosfamide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HOLOXAN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given HOLOXAN against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What HOLOXAN is used for

HOLOXAN is used to treat various types of cancer. These include:

- lymphoma, a cancer of the lymph glands (one type of lymphoma is also called Hodgkin's Disease)
- a type of cancer called sarcoma
- cancer of the testes
- breast cancer
- ovarian cancer
- cervical cancer
- lung cancer

HOLOXAN belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

HOLOXAN works by stopping cancer cells from growing and multiplying.

Your doctor may have prescribed HOLOXAN for another reason. **Ask your doctor if you have any questions about why HOLOXAN has been prescribed for you.**

HOLOXAN is often used in combination with other medicines to treat cancer.

HOLOXAN is not addictive.

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

Before you are given HOLOXAN

When you must not be given it

Do not have HOLOXAN if you have an allergy to HOLOXAN (ifosfamide).

Symptoms of an allergic reaction to HOLOXAN may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin
- dizziness or lightheadedness

Do not have HOLOXAN if you have, or have had, any of the following medical conditions, unless you have first discussed this with your doctor:

- severe liver problems
- kidney problems
- bladder problems, including a burning feeling when passing urine

- condition of the blood with a reduced number of white or red blood cells or platelets

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

HOLOXAN may cause birth defects if either the male or female is using it at the time of conception. **Both men and women taking HOLOXAN and their partners must use a reliable method of contraception during and for 6 months after receiving HOLOXAN.**

Females: Do not have HOLOXAN if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, HOLOXAN is not recommended for use during pregnancy unless you and your doctor have discussed the risks and benefits involved.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are having HOLOXAN or shortly after you have stopped having HOLOXAN.

HOLOXAN may interfere with the reproductive system in both men and women, causing loss of ability to have children. This may be irreversible in some people.

Please discuss this with your doctor.

Do not breastfeed while you are being treated with HOLOXAN.

HOLOXAN passes into the breast milk and therefore there is a possibility that the breastfed baby may be affected.

If you are not sure whether you should start having HOLOXAN, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver problems
- kidney problems
- bladder problems
- heart problems
- blood disorder with a reduced number of red or white blood cells or platelets
- convulsions, fits or seizures
- sugar diabetes
- problems with too much alcohol

Tell your doctor about any previous treatments you have had for cancer, such as other medicines, or radiation therapy.

Tell your doctor if you have had any operations in the last 3 months.

If you have not told your doctor about any of the above, tell them before you start having HOLOXAN.

Taking other medicines

Tell your doctor or pharmacist if you are having any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and HOLOXAN may interfere with each other. These include:

- other medicines used to treat cancer (eg cisplatin), radiation therapy or any other treatment which lowers your immune system
- medicines used to prevent blood clots, including warfarin
- some medicines used to treat diabetes
- allopurinol, a medicine used to treat gout
- hydrochlorothiazide, a diuretic (also called a water or fluid tablet)
- some medicines used to treat infections
- some medicines used to stop or prevent vomiting
- bupropion, a medicine to help stop smoking
- some medicines used to treat epilepsy
- some medicines used as sedatives or to relieve anxiety
- some medicines used to relieve pain
- some medicines used to help sleeping
- some anti-allergy medicines
- some vaccines

These medicines may be affected by HOLOXAN, or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while having HOLOXAN.

How HOLOXAN is given

HOLOXAN will always be given by specially trained doctors or nurses in a hospital or clinic.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

Ask your doctor if you want to know more about the dose of HOLOXAN you receive.

How it is given

HOLOXAN is given as an infusion (drip) into your veins.

HOLOXAN is always given with another medicine called UROMITEXAN (mesna) Injection or Tablets, to help prevent side effects on the bladder and urinary system.

How long it is given

HOLOXAN is usually given either as a continuous infusion over 24 hours, or as a short infusion on 3-5 consecutive days.

HOLOXAN may be given alone or in combination with other medicines to treat cancer. If it is given in combination with other medicines, further days of treatment may be needed.

The treatment is usually repeated every 2-4 weeks, depending on when any unwanted effects of the medicine have settled down. These are called cycles of chemotherapy.

Several cycles of HOLOXAN therapy may be needed depending on your response to treatment.

Overdose

As HOLOXAN is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given HOLOXAN, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of a HOLOXAN overdose include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature.

While you are having HOLOXAN

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up cycles of HOLOXAN at the appropriate times to get the best effects from your treatments.

Be sure to follow your doctor's instructions about other medicines you should take, and other things you should do.

You may need to take other medicines to help prevent unwanted effects of HOLOXAN. You may also be advised to drink extra fluid, to help prevent damage to the bladder and urinary system.

Ask your doctor or pharmacist if you have any questions.

Tell the doctor or nurse if you experience any pain during the injection of HOLOXAN.

Tell any other doctors, dentists, and pharmacists who are treating you that you are having HOLOXAN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having HOLOXAN.

Both men and women taking HOLOXAN and their partners must use a reliable method of contraception during and for 6 months after receiving HOLOXAN.

If you become pregnant while having HOLOXAN, tell your doctor.

HOLOXAN can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. **The following precautions should be taken to reduce your risk of infection or bleeding:**

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

- Avoid contact sports or other situations where you may bruise or get injured.

Things you must not do

Do not drink alcohol while you are on HOLOXAN.

Alcohol may worsen some side effects of HOLOXAN, such as nausea, vomiting and dizziness.

Do not eat grapefruit or drink grapefruit juice while you are on HOLOXAN.

Grapefruit may interact with HOLOXAN and cause it not to work as well.

Things to be careful of

Be careful driving or operating machinery until you know how HOLOXAN affects you.

As with many other medicines, HOLOXAN may cause side effects such as dizziness, drowsiness and nausea in some people. Make sure you know how you react to HOLOXAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having HOLOXAN.

Like other medicines that treat cancer, HOLOXAN may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting
- loss of appetite
- diarrhoea
- constipation
- unusual hair loss or thinning
- unusual tiredness or weakness
- no menstrual periods

These are the more common side effects of HOLOXAN.

Hair usually grows back again after treatment is stopped, although it may be of a different colour or texture.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- tiredness, headaches, being short of breath when exercising, dizziness, looking pale
- bleeding or bruising more easily than normal
- frequent infections, fever, severe chills, sore throat or mouth ulcers
- changes to breathing, cough
- sore, red mouth
- inflammation of mucous membranes (eg vagina)
- skin rash
- cramps
- blurred vision, changes in vision
- severe upper stomach pain
- tingling or numbness in fingers or toes

These may be serious side effects. You may need medical attention.

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

- blood in the urine
- pain in the bladder or difficulty passing urine
- disease of the brain - symptoms include drowsiness, confusion, hallucinations, fits or seizures, loss of consciousness
- vomiting bright red blood
- heart disease - symptoms include fatigue, chest pain, palpitations, altered heart beat
- shortness of breath, swelling of feet and ankles
- swelling and redness along a vein which is extremely tender when touched
- unexpected pain, tenderness or weakness in the muscles
- sudden sign of allergy such as rash, itching or hives on the skin, swelling of face, tongue or other parts of the body, difficulty breathing, dizziness

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

The benefits and side effects of HOLOXAN may take some time to occur. Therefore even after you have finished your HOLOXAN treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

In some cases, different cancers, especially of the bladder or the bone marrow, have occurred in patients up to several years after treatment with HOLOXAN.

Discuss any concerns you have about this with your doctor.

Storage

HOLOXAN will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25°C.

Product description

What it looks like

HOLOXAN is a white powder in a clear glass vial. It is mixed with a liquid before use. Each vial is used only once and any leftover material is discarded.

Ingredients

Active ingredient:
ifosfamide

There are no inactive ingredients in HOLOXAN.

Sponsor

Baxter Healthcare Pty Limited
(ABN 43 000 392 781)
1 Baxter Drive
Old Toongabbie NSW 2146

HOLOXAN is available in the following sizes:
1g AUST R 43608
2g AUST R 43609

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