

HOLOXAN

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.

1. Why am I receiving HOLOXAN?

HOLOXAN contains the active ingredient ifosfamide. HOLOXAN is used to treat various types of cancer. For more information, see Section [1. Why am I receiving HOLOXAN?](#) in the full CMI.

2. What should I know before receiving HOLOXAN?

Do not use if you have ever had an allergic reaction to HOLOXAN (ifosfamide). **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 receiving HOLOXAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HOLOXAN and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is HOLOXAN given?

- Your doctor or Registered Nurse will give HOLOXAN by an infusion (drip) administered intravenously (into a vein). It is always given with another medicine called UROMITEXAN (mesna). It is usually given as a continuous infusion over 24 hours, or a shorter infusion time over 3 to 5 days in a row.
- Your doctor will decide how much HOLOXAN to give you, depending on your need and on factors such as your weight, kidney function, and other chemotherapy medicines you are receiving.

More instructions can be found in Section [4. How is HOLOXAN given?](#) in the full CMI.

5. What should I know while receiving HOLOXAN?

Things you should do	<ul style="list-style-type: none">• Keep all your doctor's appointments to get the best effects from treatment, and so your progress can be checked.• Follow your doctor's instructions about other medicines you should take, and other things you should do.• For men and women of reproductive age: Use a reliable form of birth control while you are being treated with HOLOXAN and for at least 6 months after your treatment has stopped if you are male, and for 12 months after your treatment has stopped if you are female.• Call your doctor straight away if you become pregnant while you are receiving HOLOXAN.• Remind any doctor, dentist, nurse or pharmacist you visit that you are receiving HOLOXAN.• Take precautions to minimise the risk of infections and bleeding.
Things you should not do	<ul style="list-style-type: none">• Do not eat grapefruit or drink grapefruit juice while you are receiving HOLOXAN.
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 HOLOXAN affects you.• Do not drive if you experience dizziness or lightheadedness.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are receiving HOLOXAN.

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

6. Are there any side effects?

Common side effects include hair loss, nausea, vomiting, fatigue, persistent feelings of sadness, irritability, or lack of motivation, poor quality sleep. Serious side effects symptoms such as confusion, weakness, loss of memory, changes in personality, pale skin, cold hands or feet, swollen lymph nodes, frequent or unusual infections, cough, shortness of breath, fever, chills, easy bruising, bleeding of nose and gums, heavy menstrual cycle, sweet or fruity breath, appetite loss, rapid breathing, reduced sexual desire, erectile dysfunction, testicular pain or swelling in men, dark/pink urine, and painful /frequent urination. If you feel any of these symptoms, seek 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.

HOLOXAN

Active ingredient: *ifosfamide*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I receiving HOLOXAN?](#)
- [2. What should I know before I receive HOLOXAN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is HOLOXAN given?](#)
- [5. What should I know while receiving HOLOXAN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving HOLOXAN?

HOLOXAN contains the active ingredient ifosfamide. HOLOXAN is a type of chemotherapy medicine. It belongs to a group of medicines called antineoplastic or cytotoxic medicines.

HOLOXAN is used to treat various types of cancer, including:

- germ cell tumours (cancers that grow from cells that become sperm or eggs)
- sarcomas (a type of cancer in soft tissues and bones)
- lymphomas (cancer of the lymph glands)
- ovarian cancer
- cervical cancer
- lung cancer
- breast cancer

HOLOXAN works by stopping cancer cells from growing and multiplying. It is often used in combination with other medicines to treat cancer.

2. What should I know before I receive HOLOXAN?

Warnings

Do not have HOLOXAN if:

- you are allergic to ifosfamide, the active ingredient in HOLOXAN
- Always check the ingredients to make sure you can use this medicine.
- you have the following medical conditions (unless you have first discussed these with your doctor):
 - severe liver problems

- kidney or bladder problems, such as difficulty passing urine or a burning feeling when passing urine.
- a condition of the blood with a reduced number of red or white blood cells or platelets
- you have had surgery in the past few days.
- you are pregnant or breastfeeding (see '**Pregnancy and breastfeeding**')
- you are planning to become pregnant (see '**People of reproductive age**')
- you have an infection or high temperature.

If you have an infection, your doctor may decide to delay your treatment until your infection is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Check with your doctor if you:

- Have any other medical conditions, including:
 - liver problems
 - kidney problems
 - bladder problems
 - heart problems
 - diabetes
 - being overweight
 - drinking very little fluid
 - electrolyte problems, or low sodium
 - a blood disorder with a reduced number of red or white blood cells or platelets
- bone marrow problems (including cancer that has spread to the bone marrow)
- brain or nerve problems
- convulsions, fits or seizures
- other pre-existing neurological disorders
- cancer that has spread to the brain (brain metastases)
- a tumour in your lower abdomen
- problems with drinking too much alcohol
- have had an operation in the last 2 weeks
- have had previous treatment for cancer, such as other cancer medicines or radiation therapy
- take any medicines for any other conditions.

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

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 in pregnancy, especially in early pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant, to discuss the risks and benefits. See also 'People of reproductive age'.

Do not breastfeed while receiving HOLOXAN.

HOLOXAN passes into the breast milk and may affect the breast-fed baby.

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

People of reproductive age

Use a reliable form of birth control while you are being treated with HOLOXAN and for:

- at least 6 months after your treatment has stopped if you are male
- 12 months after your treatment has stopped if you are female.

HOLOXAN may cause birth defects if either males or females are being treated with it at the time of conception.

Tell your doctor if you or your partner intends to become pregnant while you or they are receiving HOLOXAN or shortly after stopping 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.

Men should talk to their doctor about sperm storage before starting treatment.

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.

Some medicines and HOLOXAN may interfere with each other. These medicines may be affected by HOLOXAN or may affect how it works.

- some other medicines used to treat cancer (such as 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, such as sulfonylureas
- allopurinol, a medicine used to treat gout
- hydrochlorothiazide, a diuretic (also called a water or fluid tablet)
- some medicines used to treat infections, such as aminoglycosides, acyclovir, amphotericin b, rifampicin
- some medicines used to stop or prevent nausea and vomiting
- bupropion, a medicine used to help stop smoking
- some medicines used to treat epilepsy or seizures, such as phenobarbital, phenytoin, primidone
- 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
- some medicines used to treat schizophrenia or bipolar disorder, such as chlorpromazine
- some medicines used to treat thyroid hormone problems, such as triiodothyronine
- some medicines used to help people stop drinking alcohol, such as disulfiram
- suxamethonium, a muscle relaxant used in operations

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

4. How is HOLOXAN given?

How it is given

- Your doctor or Registered Nurse will give HOLOXAN by an infusion (drip) administered intravenously (into a vein).
- It is always given with another medicine called UROMITEXAN (mesna) Injection or Tablets, to help prevent side effects on the bladder and urinary system.
- Your dose may be given on a single day, over 24 hours
- Your dose may be divided into shorter infusion sessions over 3 to 5 days.
- Doses are repeated every 2 to 4 weeks, in what is called cycles of chemotherapy.
- Several cycles may be needed depending on your response to treatment.

How much is given

- Your doctor will decide how much HOLOXAN to give you.
- The amount depends on your condition, and on factors such as your weight, kidney function, and other chemotherapy medicines you are receiving.

If you receive too much HOLOXAN

The doctor or nurse giving you HOLOXAN is highly trained and qualified, so it is unlikely that you will be given an overdose.

If you think that you have used too much HOLOXAN, 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 receiving HOLOXAN?

Things you should do

- Keep all your doctor's appointments to get the best effects from treatment, and so your progress can be checked.

It is important to have your follow-up doses at the appropriate times to get the best treatment outcomes.

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

- 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.

- For men and women of reproductive age: Use a reliable form of birth control while you are being treated with HOLOXAN and for at least **6 months after your treatment has stopped if you are male**, and for **12 months after your treatment has stopped if you are female**.

HOLOXAN may cause birth defects if either males or females are being treated with it at the time of conception.

Tell your doctor if you or your partner intends to become pregnant while you or they are receiving HOLOXAN or shortly after stopping HOLOXAN.

Tell your doctor straight away if you:

- become pregnant while receiving HOLOXAN.
- experience any pain during the injection of HOLOXAN

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

Things you should not do

- **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.

Reducing the risk of infection and bleeding

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.

To reduce the risk of infection and bleeding, follow these precautions:

- 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.

Driving or using machines

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

As with many other medicines, HOLOXAN may cause nausea, dizziness or light-headedness 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.

Drinking alcohol

Do not drink alcohol while you are on HOLOXAN.

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

Looking after your medicine

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.

Getting rid of any unwanted medicine

HOLOXAN is for single use, and for one person only. Your doctor or Registered Nurse will discard any unused medicine. They will not save unused portions for later, either for you or anyone else.

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.

Less serious side effects

Less serious side effects	What to do
<p>Gut related:</p> <ul style="list-style-type: none"> • nausea, vomiting • loss of appetite • diarrhoea or constipation • excess saliva • sore red mouth <p>Hair and skin related:</p> <ul style="list-style-type: none"> • unusual hair loss or thinning (which may grow back after treatment with different colour or texture) • redness, swelling, and pain on palms of hands and soles of feet • skin redness and inflammation at previous radiation sites • change in skin or nail colour/texture <p>At the infusion-site:</p> <ul style="list-style-type: none"> • pain, inflammation, itchiness swelling or redness at the site of administration, or the vein (into which the solution is infused) <p>Others:</p> <ul style="list-style-type: none"> • unusual tiredness or weakness • no menstrual periods • irritated eyes, conjunctivitis • hearing changes, ringing in the ears • muscle twitching • excessive sweating • sweet or fruity breath 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Kidney and bladder related:</p> <ul style="list-style-type: none"> • pain in the bladder or back • pain or difficulty passing urine • blood in the urine • decreased or increased urine output • dark urine • weight gain • swelling of the hands, feet or other 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious</p>

<p>parts of the body due to fluid build up</p> <ul style="list-style-type: none"> • needing to urinate more often than usual • difficulty controlling urine or leaking • trouble fully emptying the bladder • bone pain or softness over time • feeling very thirsty <p>Blood count related:</p> <ul style="list-style-type: none"> • frequent infections • fever or severe chills • sore throat or mouth ulcers • tiredness, headaches, dizziness, being short of breath when exercising, looking pale • bleeding or bruising more easily than normal, nose bleeds, heavy menstrual bleeding • tiny red, purple, or brown spots on the skin <p>Allergic reaction related: Sudden signs of:</p> <ul style="list-style-type: none"> • rash, itching or hives on the skin • swelling of the face, tongue or other parts of the body • difficulty breathing • fever • dizziness <p>Brain and nerve related:</p> <ul style="list-style-type: none"> • drowsiness or sleepiness • confusion or forgetfulness • restlessness, issues with sleep quality, or difficulty falling asleep • hallucinations • persistent feelings of sadness or lack of motivation • anxiety, agitation, sudden mood swings, irritability, extreme excitement • unsteady walking or balance, shaking or tremors slurred speech • slow thinking and speech problems (like repeating words, excessive talking or unable to talk) • fits or seizures • loss of consciousness • tingling or numbness in fingers or toes • blurred vision, changes in vision <p>Gut and liver related:</p> <ul style="list-style-type: none"> • stomach cramps • severe upper stomach pain • vomiting bright red blood or coffee-ground like material • diarrhoea with blood and mucous • loss of bowel control 	<p>side effects.</p>
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- sudden weight gain, swelling of stomach, build-up of fluid in stomach
- yellowing of the skin and/or eyes
- pale or light-coloured stools

Heart and lung related:

- chest pain, tightness, pressure or discomfort
- shortness of breath, rapid breathing, wheezing, cough
- palpitations or altered heartbeat
- swelling of legs, feet, ankles, belly or chest
- feeling dizzy, weak or fatigued

Pregnancy and conception related:

- premature menopause
- infertility
- reduced sexual desire, erectile dysfunction, testicular pain or swelling in men (symptoms of changes sperm count)
- change in testicle size
- foetal harm (growth restriction)

Others

- inflammation of the mucous membranes (e.g. vagina)
- swelling and redness along a vein which is extremely tender when touched
- unexpected pain, tenderness or weakness in the muscles
- widespread skin pain and rash, with blisters and large areas of peeling skin
- sores, swelling and crusting on the mucous membranes, including the mouth, eyes and vagina
- areas of dead, blackened skin tissue

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 HOLOXAN contains

Active ingredient (main ingredient)	ifosfamide
Other ingredients (inactive ingredients)	None

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

What HOLOXAN looks like

HOLOXAN is a white powder in a clear glass vial. It is mixed with a liquid before use. It is available in the following strengths:

- 500mg – Aust R 43606
- 1g – Aust R 43608
- 2g – Aust R 43609

Not all strengths may be marketed.

Who distributes HOLOXAN

Baxter Healthcare Pty Ltd
 1 Baxter Drive
 Old Toongabbie
 NSW 2146
 Australia

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

In some cases, patients have developed various cancers, especially of the bladder or bone marrow, several years after treatment with HOLOXAN.

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. Some side effects can only be detected by your doctor by physical examination, laboratory tests or scans.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

This leaflet was prepared in December 2025.

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