

ENDOXAN

Cyclophosphamide Powder for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ENDOXAN.

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 ENDOXAN 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 ENDOXAN is used for

ENDOXAN is used in the treatment of various types of cancer.

It can also be used in some diseases of the immune system, and to prevent rejection of organ transplants.

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

In cancer, ENDOXAN works by stopping cancer cells from growing and multiplying.

In other conditions, it works by lowering the immune system.

Your doctor may have prescribed ENDOXAN for another reason.

Ask your doctor if you have any questions about why ENDOXAN has been prescribed for you.

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

ENDOXAN is not addictive.

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

Before you are given ENDOXAN

When you must not be given it

Do not have ENDOXAN if you have an allergy to ENDOXAN (cyclophosphamide).

Symptoms of an allergic reaction 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 ENDOXAN if you have any of the following medical conditions, unless you have first discussed this with your doctor:

- condition of the blood with a reduced number of red or white blood cells or platelets
- bladder problems, such as difficulty passing urine, or burning feeling when passing urine.

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.

Do not have ENDOXAN if you have had surgery in the last few days.

ENDOXAN may cause birth defects if either the male or female is being treated with it at the time of conception.

You should use a reliable form of birth control while you are being treated with ENDOXAN and for at least 3 months after your treatment has stopped. Please discuss this with your doctor.

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

Like most medicines used to treat cancer, ENDOXAN is not recommended for use during pregnancy, especially in the first 3 months of 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 using ENDOXAN or shortly after you have stopped using ENDOXAN.

ENDOXAN 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 ENDOXAN.

ENDOXAN passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you are not sure whether you should start having ENDOXAN, 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
- blood disorder with a reduced number of red or white blood cells or platelets
- diabetes
- lowered immunity due to diseases including HIV / AIDS or cancer

Tell your doctor if you have had an operation to remove your adrenal glands.

The doses of your medicines may need to be adjusted.

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

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

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 ENDOXAN may interfere with each other. These include:

- some other medicines used to treat cancer (including busulfan), radiation therapy, or any other treatment which lowers your immune system
- suxamethonium, a muscle relaxant used in operations
- some medicines used as sedatives or to relieve anxiety
- hydrochlorothiazide, a diuretic (also called a water or fluid tablet)
- phenytoin and phenobarbitone, medicines used to treat epilepsy
- chloramphenicol, a medicine used to treat bacterial infections
- allopurinol, a medicine used to treat gout
- indomethacin, a medicine used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- some medicines used to treat diabetes
- some vaccines (ask your doctor)
- alcohol

These medicines may be affected by ENDOXAN, 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 ENDOXAN.

How ENDOXAN is given

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

How much is given

ENDOXAN may be given alone or in combination with other medicines.

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 ENDOXAN you receive.

How it is given

ENDOXAN is given as an infusion (drip) into your veins (intravenously), usually over 30-60 minutes.

How long it is given

ENDOXAN may be given on one day, or the dose may be divided over more than one day. This is repeated every 3-4 weeks, depending on when your blood cell numbers return to acceptable levels, and any other unwanted effects of the medicine have settled down. These are called cycles of chemotherapy.

Several cycles of ENDOXAN treatment may be needed, depending on your response to treatment.

Overdose

As ENDOXAN 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 ENDOXAN, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

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

While you are having ENDOXAN

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 doses of ENDOXAN at the appropriate times to get the best effects from your treatment.

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

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

Both men and women taking ENDOXAN and their partners must use a reliable method of contraception during and for 3 months after receiving ENDOXAN.

ENDOXAN may cause birth defects if either the male or female is being treated with it at the time of conception.

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

ENDOXAN 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 ENDOXAN.

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

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

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

Things to be careful of

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

As with many other medicines, ENDOXAN may cause nausea, dizziness or light-headedness in some people. Make sure you know how you react to ENDOXAN 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 ENDOXAN.

Like other medicines that treat cancer, ENDOXAN 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:

- loss of appetite
- feeling sick, vomiting
- diarrhoea or constipation
- no menstrual periods
- unusual hair loss or thinning
- change in colour of nails, palms of hands or soles of feet
- skin rash
- inflammation of the skin and mucosa (eg vagina)
- dizziness

These are the more common side effects of ENDOXAN.

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

- fever, infection
- sore red mouth, mouth ulcers
- tiredness, headaches, dizziness, being short of breath when exercising, looking pale
- bleeding or bruising more easily than normal, nose bleeds
- yellowing of the skin and/or eyes
- blurred vision
- severe upper stomach pain
- shortness of breath, difficulty breathing, coughing

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:

- changes in the way the heart beats, chest pain
- pain in the bladder or back, difficulty passing urine, blood in the urine
- diarrhoea with red blood and mucous, pain and fever
- sudden weight gain, swelling of stomach, build up of fluid in stomach
- impaired consciousness, memory loss, personality change, tremor, stupor, coma
- seizures, fits or convulsions

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 ENDOXAN may take some time to occur. Therefore even after you have finished your ENDOXAN 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 ENDOXAN.

Discuss any concerns you have about this with your doctor.

Storage

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

Product description

What it looks like

ENDOXAN 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:

- cyclophosphamide

There are no inactive ingredients in ENDOXAN.

Sponsor

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

ENDOXAN is available in the following sizes:

500mg	AUST R 82127
1g	AUST R 82129
2g	AUST R 82128

Date of preparation of this leaflet:
6 May 2003

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