

CYCLONEX® 50 mg

Tablets

Cyclophosphamide monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CYCLONEX®. 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 taking CYCLONEX against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What CYCLONEX is used for

CYCLONEX is used to treat certain types of cancer such as:

- malignant lymphoma, a cancer of the lymph glands
- multiple myeloma, type of blood cancer
- leukaemia, type of blood cancer
- mycosis fungoides, a cancer of the lymph glands which affects the skin
- neuroblastoma, a cancer of nerves and the adrenal glands
- ovarian cancer
- a type of cancer called retinoblastoma
- breast cancer and
- some types of lung cancers

CYCLOBLASTIN is also used to:

- treat certain types of diseases of the immune system when other treatments have not worked
- prevent the body from rejecting organ transplants.

How CYCLONEX works

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

In the treatment of cancer, CYCLONEX works by stopping cancer cells from growing and multiplying.

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

CYCLONEX is not addictive.

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

Before you take CYCLONEX

When you must not take CYCLONEX

Do not use CYCLONEX if you have an allergy to:

- cyclophosphamide, the active ingredient in CYCLONEX
- any of the other ingredients in CYCLONEX listed at the end of this leaflet.

Symptoms of an allergic reaction to CYCLONEX may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- light-headedness
- back pain.

Do not use CYCLONEX if you have an infection.

Do not use CYCLONEX if you have any of the following medical conditions:

- cystitis (pain in the bladder or back, blood in urine)
- urinary infection
- difficulty passing urine
- drug or radiation induced inflammation of the urinary tract.

Do not use CYCLONEX if you have had major surgery in the last 4 to 8 days.

Do not use CYCLONEX in the first 3 months of pregnancy. If you are more than 3 months pregnant, discuss using CYCLOBLASTIN with your doctor before starting the treatment.

Do not use CYCLONEX after the expiry date (EXP) printed on the pack.

Do not use CYCLONEX if the packaging is torn or shows signs of tampering.

If you are not sure whether you should use CYCLONEX, talk to your doctor.

Before you start to take CYCLONEX

Tell your doctor if you have an allergy to:

- cyclophosphamide, the active ingredient in CYCLONEX
- any of the other ingredients in CYCLONEX listed at the end of this leaflet
- 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
- heart problems (including a heart attack)
- acute porphyria (a blood disorder)
- diabetes
- leukopenia (lack of white blood cells resulting in frequent infections, fever, severe chills, sore throat or mouth ulcers)
- thrombocytopenia (low blood platelet count resulting in bleeding or bruising more easily than normal)
- problems with your adrenal glands.

Tell your doctor if you are taking insulin or other drugs for diabetes, barbiturates or you are having or have recently had corticosteroid therapy.

Tell your doctor if you have had previous chemotherapy, x-ray or radiotherapy.

Tell your doctor if you are or have been taking any other medicine for cancer.

Tell your doctor if you are pregnant or intend to become pregnant. CYCLONEX should not be used during pregnancy, particularly in the first three months of pregnancy.

If there is any need to consider giving you CYCLONEX during your pregnancy, your doctor or

pharmacist will discuss with you the benefits and risks of using it.

Use a proven method of birth control, such as the contraceptive pill or a condom, while taking the medicine and for at least 12 weeks after stopping treatment.

The medicine may cause birth defects if either you or your partner is taking it.

If you become pregnant while using this medicine, tell your doctor immediately.

Following treatment with CYCLONEX you or your partner may not be able to become pregnant. Ask your doctor to discuss this with you.

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines, procedures and CYCLONEX may interfere with each other. These include:

- radiation therapy or any other treatment which lowers your immune system
- allopurinol, a medicine used to treat gout
- hydrochlorothiazide, a medicine used to reduce excess fluid
- phenobarbitone and phenytoin, medicines used to treat epilepsy
- corticosteroids such as prednisone
- barbiturates, benzodiazepines and chloral hydrate, medicines used to help you relax or sleep
- chloramphenicol, a medicine used to treat serious bacterial infections

- sulphaphenazole, a medicine used to treat bacterial infections
- chloroquine, a medicine used to treat malaria
- imipramine, a medicine used to treat depression
- phenothiazines, medicines used to treat nausea, vomiting, psychotic disorders, depression and anxiety
- potassium iodide, a medicine used to treat fungal infections and iodine deficiency disorders
- vitamin A
- digoxin, a medicine used to treat irregular heartbeat
- medicines used in general anaesthesia
- indomethacin, a medicine used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- medicines given to control diabetes
- vaccines, medicines used to prevent diseases
- anticoagulants such as warfarin used to thin out the blood
- medicines used in the treatment of cancer such as anthracyclines (doxorubicin) and busulfan.

These medicines may be affected by CYCLONEX or they may affect how well CYCLONEX works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

How to take CYCLONEX

When it is given

It is advisable that you take your dose in the morning.

How much to take

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and the effect on your bone marrow of any previous treatment you may have had with x-ray or chemotherapy medicines.

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

How to take it

Take the tablets exactly as instructed by your doctor.

Always read the pharmacist's label to check the exact dose and how often to take it.

Only take your dose on the days agreed with your doctor or pharmacist.

The dose depends on the condition this medicine is being used for.

Take the tablets at about the same time of day.

Taking the tablets at the same time of day will have the best effect. It will also help you to remember when to take the medicine.

How long to take it

Your doctor will decide how long to continue your treatment with CYCLOBLASTIN.

If you forget to take it

If you forget to take a dose, ask your doctor for advice.

Do not use a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126) or go to accident and emergency at your nearest hospital, if you think you or

anyone else may have taken too much CYCLONEX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking CYCLONEX

Things you must do

Drink plenty of fluids before taking your medication and for 24 hours after you've taken your medication.

Empty your bladder frequently, especially for 24 hours after you've taken your medication.

Keep all your doctor's appointments so your progress can be checked. Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell all doctors, dentists and pharmacists who are treating you that you are having treatment with CYCLONEX.

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

If you plan to have surgery that needs a general anaesthetic, it is very important you tell your doctor or dentist that you are having treatment with CYCLONEX.

If you become pregnant while you are having treatment with CYCLONEX, tell your doctor immediately.

Avoid grapefruit and grapefruit juice.

Grapefruit contains a substance that can reduce the effect of CYCLONEX.

Avoid drinking alcohol while taking CYCLONEX.

CYCLONEX 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 give CYCLOBLASTIN to anyone else, even if they have the same condition as you.

Do not use CYCLONEX to treat any other complaints unless your doctor tells you to.

Avoid any contact with CYCLONEX tablets. Contact with the skin or eyes should be treated immediately by washing the affected area with water or sodium bicarbonate solution. Seek medical attention.

Things to be careful of

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

As with other antineoplastic medicines, CYCLONEX may cause dizziness and tiredness in some people. Make sure you know how you react to CYCLONEX before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or tired. If this occurs, do not drive. If you drink alcohol, the dizziness may be worse.

Possible side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with CYCLONEX.

Like other medicines that treat cancer, CYCLONEX 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:

- runny or blocked nose; sneezing, facial pressure or pain (rhinitis)
- headache
- dizziness, nausea, vomiting
- loss of appetite (anorexia)
- stomach pain or discomfort
- diarrhoea or constipation
- irregular or no menstrual periods
- unusual hair loss or thinning; hair becoming coarse
- darkening of skin; dry skin
- nail changes; darkening of the fingernails
- skin rash
- sudden reddening of the face and neck

- red, itchy rash on the back of the hands, palms and or feet
- recurrent, short periods of blurred vision.

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

- mouth ulcers
- sore mouth
- yellowing of the skin and/or eyes (jaundice)
- changes to breathing
- gout - painful swollen joints
- painful urination; increased frequency of urination
- sudden weight change; build-up of fluid around the stomach.

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

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

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylactic reaction);
- symptoms of bone marrow suppression (a disease of the blood where red and white blood cell numbers are reduced). These include tiredness, headaches, dizziness, being short of breath when exercising, looking pale, frequent infections, fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal, nose bleeds.
- diarrhoea with red blood and mucus, pain and fever (haemorrhagic colitis)
- severe diarrhoea
- blood in the urine
- lower abdominal pain
- chest pain
- altered heartbeat
- fits
- 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

After treatment with CYCLONEX

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep tablets in a cool dry place where the temperature will stay below 25°C and protected from light.

Do not store CYCLONEX tablets or any other medicines in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep CYCLONEX tablets where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product description

What it looks like

CYCLONEX 50 mg film coated tablets are brown to pinkish and have a round convex shape.

The tablets are supplied in Al/Al blister packs, containing 50 tablets.

Ingredients

Each tablet contains 50 mg of cyclophosphamide, as the active ingredient.

The tablets also contain the following inactive ingredients:

- cellulose-microcrystalline
- lactose monohydrate
- croscarmellose sodium
- magnesium stearate
- colouring agent Opadry Pink.

This medicine is gluten-free and sucrose free.

Australian Registration Number

CYCLONEX 50 mg tablets can be identified by the Australian Register Number on the carton label: AUST R 297901

Sponsor

Supplied in Australia by:

Zenex Pharmaceuticals Pty Ltd
Level 6, 141 Flinders Lane
Melbourne, Victoria 3000
Australia

For medical enquiries call 1800 931 986.

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