

# CYCLOBLASTIN® Tablets and Powder for Injection

*Cyclophosphamide*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about CYCLOBLASTIN. 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 CYCLOBLASTIN 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 CYCLOBLASTIN is used for

CYCLOBLASTIN 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 CYCLOBLASTIN works

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

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

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

CYCLOBLASTIN is not addictive.

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

### Before you are given CYCLOBLASTIN

#### When you must not be given CYCLOBLASTIN

**Do not use CYCLOBLASTIN if you have an allergy to:**

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

Symptoms of an allergic reaction to CYCLOBLASTIN 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 CYCLOBLASTIN if you have an infection.**

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

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

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

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

### Before you are given CYCLOBLASTIN

**Tell your doctor if you have an allergy to:**

- cyclophosphamide, the active ingredient in CYCLOBLASTIN
- any of the other ingredients in CYCLOBLASTIN 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. CYCLOBLASTIN should not be used during pregnancy, particularly in the first three months of pregnancy.**

If there is any need to consider giving you CYCLOBLASTIN 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 CYCLOBLASTIN 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 CYCLOBLASTIN.**

### 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 CYCLOBLASTIN 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 heart beat
- 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 CYCLOBLASTIN or they may affect how well CYCLOBLASTIN 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 CYCLOBLASTIN.

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## How CYCLOBLASTIN is given

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### *How it is given*

CYCLOBLASTIN will be given to you either by injection into a vein or as a tablet by mouth.

### *When it is given*

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

### *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 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 CYCLOBLASTIN you receive.**

### *How to take it*

#### **Injection**

CYCLOBLASTIN injection will only be given to you by a doctor or nurse.

#### **Tablets**

**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 it is given*

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 CYCLOBLASTIN. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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

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## While you are taking CYCLOBLASTIN

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### *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 CYCLOBLASTIN.**

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

**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 CYCLOBLASTIN.**

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

### **Avoid grapefruit and grapefruit juice.**

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

### **Avoid drinking alcohol while taking CYCLOBLASTIN.**

CYCLOBLASTIN 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 CYCLOBLASTIN to treat any other complaints unless your doctor tells you to.**

**Avoid any contact with CYCLOBLASTIN.**

**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 CYCLOBLASTIN affects you.**

As with other antineoplastic medicines, CYCLOBLASTIN may cause dizziness and tiredness in some people. Make sure you know how you react to CYCLOBLASTIN 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.

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## Side effects

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

Like other medicines that treat cancer, CYCLOBLASTIN 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 heart beat
- 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 CYCLOBLASTIN may take some time to occur. Therefore, even after you have finished your CYCLOBLASTIN treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.**

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## After treatment with CYCLOBLASTIN

### *Storage*

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

**Keep tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store CYCLOBLASTIN or any other medicines in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.** Heat and dampness can destroy some medicines.

**Keep CYCLOBLASTIN 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.

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## Product description

### *What it looks like*

CYCLOBLASTIN is available as a 1000 mg injection and a 50 mg tablet.

The injection is a white crystalline powder for dilution available in packs of 1 vial. Each vial is used only once and any leftover material is discarded.

The 50 mg tablets are brown and have a round convex shape.

CYCLOBLASTIN 50 mg tablets are available in bottles of 50 tablets.

### *Ingredients*

The active ingredient in CYCLOBLASTIN is cyclophosphamide.

There are no inactive ingredients in CYCLOBLASTIN injection.

CYCLOBLASTIN tablets also contain microcrystalline cellulose, maize starch, pregelatinised maize starch, lactose, gelatin, sodium stearyl fumarate, magnesium stearate, macrogol 6000, sucrose, povidone, calcium carbonate, carnauba wax and a brown colouring agent (Opalux brown AS-9486).

### *Identification*

CYCLOBLASTIN injection can be identified by the Australian Register Number on the carton label:

AUST R 93606 (1000 mg).

CYCLOBLASTIN 50 mg tablets can be identified by the Australian Register Number on the carton label:

AUST R 73468.

### *Manufacturer and Supplier*

CYCLOBLASTIN is made by Orion Corporation in Finland and supplied in Australia by:

Pfizer Australia Pty Ltd  
 ABN 50 008 422 348  
 38-42 Wharf Road  
 West Ryde NSW 2114  
 Australia

For medical enquiries call 1800 675 229.

This leaflet was revised in August 2005.

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