CYCLOPHOSPHAMIDE-REACH

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 using CYCLOPHOSPHAMIDE-REACH?

CYCLOPHOSPHAMIDE-REACH contains the active ingredient cyclophosphamide. CYCLOPHOSPHAMIDE-REACH is used in the treatment of various types of cancer.

For more information, see Section 1. Why am I using CYCLOPHOSPHAMIDE-REACH? in the full CMI.

2. What should I know before I use CYCLOPHOSPHAMIDE-REACH?

Do not use if you have ever had an allergic reaction to CYCLOPHOSPHAMIDE-REACH or any of the ingredients listed at the end of the CMI.

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 I use CYCLOPHOSPHAMIDE-REACH? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CYCLOPHOSPHAMIDE-REACH 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 do I use CYCLOPHOSPHAMIDE-REACH?

CYCLOPHOSPHAMIDE-REACH will always be given by specially trained doctors or nurses in a hospital or clinic.

CYCLOPHOSPHAMIDE-REACH 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.

More instructions can be found in 4. How do I use CYCLOPHOSPHAMIDE-REACH? in the full CMI.

5. What should I know while using CYCLOPHOSPHAMIDE-REACH?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using CYCLOPHOSPHAMIDE-REACH. Both men and women being given CYCLOPHOSPHAMIDE-REACH and their partners must use a reliable method of contraception during and for 3 months after receiving CYCLOPHOSPHAMIDE-REACH. 	
Things you should not do	 you are allergic to cyclophosphamide, or any of the ingredients listed at the end of this leaflet. Do not eat grapefruit or drink grapefruit juice while you are on CYCLOPHOSPHAMIDE-REACH. 	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how CYCLOPHOSPHAMIDE-REACH affects you.	
Drinking alcohol	Do not drink alcohol while you are on CYCLOPHOSPHAMIDE-REACH. Alcohol may worsen some side effects of CYCLOPHOSPHAMIDE-REACH, such as nausea, vomiting or dizziness.	

For more information, see Section 5. What should I know while using CYCLOPHOSPHAMIDE-REACH? in the full CMI.

6. Are there any side effects?

There are less serious, serious and very serious side effects that you need to be aware of.

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.

CYCLOPHOSPHAMIDE-REACH

Active ingredient(s): cyclophosphamide

Consumer Medicine Information (CMI)

This leaflet provides important information about using CYCLOPHOSPHAMIDE-REACH. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CYCLOPHOSPHAMIDE-REACH.

Where to find information in this leaflet:

- 1. Why am I using CYCLOPHOSPHAMIDE-REACH?
- 2. What should I know before I use CYCLOPHOSPHAMIDE-REACH?
- 3. What if I am taking other medicines?
- 4. How do I use CYCLOPHOSPHAMIDE-REACH?
- 5. What should I know while using CYCLOPHOSPHAMIDE-REACH?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using CYCLOPHOSPHAMIDE-REACH?

CYCLOPHOSPHAMIDE-REACH contains the active ingredient cyclophosphamide. CYCLOPHOSPHAMIDE-REACH belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

CYCLOPHOSPHAMIDE-REACH 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.

In cancer, CYCLOPHOSPHAMIDE-REACH works by stopping cancer cells from growing and multiplying. In other conditions, it works by lowering the immune system.

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

CYCLOPHOSPHAMIDE-REACH is often used in combination with other medicines to treat cancer.

2. What should I know before I use CYCLOPHOSPHAMIDE-REACH?

Warnings

Do not use CYCLOPHOSPHAMIDE-REACH if:

 you are allergic to cyclophosphamide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- · have any other medical conditions
 - 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.
- take any medicines for any other condition
- you have had surgery in the last few days.

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

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 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.

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

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH and for at least 3 months after your treatment has stopped.

Please discuss this with your doctor.

Females: Do not have CYCLOPHOSPHAMIDE-REACH if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH or shortly after you have stopped using CYCLOPHOSPHAMIDE-REACH.

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH.

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH, talk to your doctor or pharmacist.

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 may interfere with CYCLOPHOSPHAMIDE-REACH and affect how it works including:

- 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 phenobarbital, medicines used to treat epilepsy

- chloramphenicol, a medicine used to treat bacterial infections
- allopurinol, a medicine used to treat gout
- indometacin, 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 CYCLOPHOSPHAMIDE-REACH, 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 CYCLOPHOSPHAMIDE-REACH.

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

4. How do I use CYCLOPHOSPHAMIDE-REACH?

CYCLOPHOSPHAMIDE-REACH will always be given by specially trained doctors or nurses in a hospital or clinic.

How much is given

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH you receive.

How it is given

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

How long it is given

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH treatment may be needed, depending on your response to treatment.

If you use too much CYCLOPHOSPHAMIDE-REACH

If you think that you have been given too much CYCLOPHOSPHAMIDE-REACH, 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.

As CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH, tell your doctor immediately or go to Emergency Department at your nearest hospital. You may need urgent medical attention.

Symptoms of an CYCLOPHOSPHAMIDE-REACH overdose include the side effects listed below in the 'Are there any side effects?' section, but are usually of a more severe nature.

5. What should I know while using CYCLOPHOSPHAMIDE-REACH?

Things you should 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 CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH. 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 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 CYCLOPHOSPHAMIDE-REACH if you have had surgery in the last few days.

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

CYCLOPHOSPHAMIDE-REACH 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 CYCLOPHOSPHAMIDE-REACH, tell your doctor.

CYCLOPHOSPHAMIDE-REACH 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.

Remind any doctor, dentist or pharmacist you visit that you are using CYCLOPHOSPHAMIDE-REACH.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CYCLOPHOSPHAMIDE-REACH affects you.

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

Drinking alcohol

Do not drink alcohol while you are on CYCLOPHOSPHAMIDE-REACH. Patients receiving treatment with cyclophosphamide should abstain from drinking alcoholic beverages.

Alcohol may worsen some side effects of CYCLOPHOSPHAMIDE-REACH, such as nausea, vomiting or dizziness.

Things you should not do

Do not eat grapefruit or drink grapefruit juice while you are on CYCLOPHOSPHAMIDE-REACH.

Grapefruit may interact with CYCLOPHOSPHAMIDE-REACH and cause it not to work as well.

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
 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 CYCLOPHOSPHAMIDE-REACH. Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 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 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very Serious side effects

Serious side effects		What to do
•	changes in the way the heart	Tell your doctor
	beats, chest pain	or nurse
•	pain in the bladder or back,	immediately, or
	difficulty passing urine, blood in	go straight to

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

the Emergency Department at your nearest hospital

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.

The benefits and side effects of CYCLOPHOSPHAMIDE-REACH may take some time to occur. Therefore even after you have finished your CYCLOPHOSPHAMIDE-REACH 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 cyclophosphamide. Discuss any concerns you have about this with your doctor.

Reporting side effects

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

Active ingredient	cyclophosphamide
(main ingredient)	
Other ingredients	mannitol
(inactive ingredients)	

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

What CYCLOPHOSPHAMIDE-REACH looks like

CYCLOPHOSPHAMIDE-REACH 500 mg White to off white Lyophilised cake or powder in 50 mL Type-I clear moulded glass vial with 20 mm Rubber stopper and sealed with 20

mm aluminium seal having polypropylene dis (Aust R 394170).

CYCLOPHOSPHAMIDE-REACH 1000 mg White to off white Lyophilized cake or powder in 50 mL Type-I clear moulded glass vial with 20mm Rubber stopper and sealed with 20 mm aluminium seal having polypropylene dis (Aust R 394171).

Who distributes CYCLOPHOSPHAMIDE-REACH

Reach Pharmaceuticals Pty Ltd Ground Floor, Corporate One 84 Hotham Rd, Preston VIC 3072 medical@reach-pharma.com

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