# PACKAGE LEAFLET: **INFORMATION FOR THE** PATIENT

# **Cyclophosphamide** Tablets 50 mg

# Cvclophosphamide monohvdrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist. • This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as vours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes possible side effects not listed in this leaflet. See section 4.

Throughout this leaflet, Cyclophosphamide Tablets 50 mg will be called Cyclophosphamide.

# Important things to know about Cyclophosphamide

Your doctor has prescribed Cyclophosphamide because you have cancer that can be treated

Cyclophosphamide is a medicine that kills cancer cells but, as a result, also attacks normal cells. It can therefore have a number of side effects. Your doctor will not give you Cyclophosphamide unless he or she thinks that your cancer is more of a risk to you than any possible side effects. Your doctor will check you regularly and treat any side effects where possible.

## Cyclophosphamide

- will reduce your blood cell count, which may make you feel tired and be more likely to get infections.
- can affect your kidneys and bladder. You may be given another medicine called Mesna to help prevent any damage. If you notice blood in your urine, tell your doctor immediately.
- like most anti-cancer or chemotherapy medicines, you may lose your hair (anything from thinning to total loss), although it should start to grow back once your treatment has finished. It may also make you feel sick or be sick. Your doctor can give you advice or medicines to help.
- Men or women should not have a child during treatment with mide or for at least 6 months after treat You should use an effective contraceptive. Ask your doctor for

Now read the rest of this leaflet. It includes other important nformation on the use of Cyclophosphamide that might be especially important for you.

## In this leaflet:

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**Cyclophosphamide** 

- . What Cyclophosphamide is and what it is used for
- 2. What you need to know before you take Cyclophosphamide
- 3. How to take Cyclophosphamide
- 4. Possible side effects
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## 1 What Cyclophosphamide is and what it is used for

Cvclophosphamide is a cvtotoxic drug or anti-cancer drug. It works by killing cancer cells, this is sometimes called 'chemotherapy'. It is used to treat lots of different cancers. Cyclophosphamide is often used together with other anti-cancer drugs or radiotherapy. Occasionally, some doctors may prescribe Cyclophosphamide for other conditions not related to cancer, your doctor will tell you if this applies to you

# 2 What you need to know before you take Cyclophosphamide

#### Do not take Cyclophosphamide if:

• you have ever had an allergic reaction to the active ingredient or any of the other ingredients (listed in Section 6). An allergic reaction can include shortness of breath, wheezing, rash, itching or swelling of the face and lips

- your bone marrow is not working properly (especially if you have previously had chemotherapy or radiotherapy). You will have blood tests to check how well your bone marrow is working
- you have a urinary tract infection, which can be recognised as pain when passing urine (cystitis)
- you currently have any infections • you have ever had kidney or bladder problems as a result of
- previous chemotherapy or radiotherapy vou have a condition which decreases your ability to urinate
- (Urinary outflow obstruction)

# Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cvclophosphamide if:

- you are already having, or have recently had, radiotherapy or chemotherapy
- vou have diabetes
- you have liver or kidney problems. Your doctor will check how well your liver and kidneys are working by doing a blood test
- you have had your adrenal glands removed
- you have heart problems or have had radiotherapy in the area of vour heart
- you have poor general health or are frail
- vou are elderly.

### Take special care with Cyclophosphamide

- Cyclophosphamide can have effects on your blood and immune
- Blood cells are made in your bone marrow. Three different types of blood cell are made: - red blood cells, which carry oxygen around your body
- white blood cells, which fight infection, and
- platelets, which help your blood to clot.
- After taking Cyclophosphamide, your blood count of the three types of cells will drop. This is an unavoidable side effect of phosphamide. Your blood count will reach its lowest level about 5 to 10 days after you start taking Cyclophosphamide and will stay low until a few days after you finish the course. Most people ver to a normal blood count within 21 to 28 days. If you hav had a lot of chemotherapy in the past, it may take a little longer to return to normal.
- · You may be more likely to get infections when your blood count drops. Try to avoid close contact with people who have coughs, colds and other infections. Your doctor will treat you with appropriate medicine if they think you have, or are at risk, of an
- Your doctor will check that the number of red blood cells white blood cells and platelets is high enough before and during your treatment with Cyclophosphamide. They may need to reduce the amount you are given or delay your next dose.
- Cvclophosphamide can affect wound healing. Keep any cuts clean and dry, and check they are healing normally.
- It is important to keep your gums healthy, as mouth ulcers and infections can occur. Ask your doctor about this if you are unsure.
- Cyclophosphamide can damage the lining of your bladder, causing bleeding into your urine and pain on urination. Your doctor knows this can happen and, if necessary, he or she will give you a nedicine called Mesna which will protect your bladder
- Mesna can either be given to you as a short injection, or mixed into the drip solution with your Cyclophosphamide, or as tablets.
- More information on Mesna can be found in the Patient Information Leaflet for Mesna Injection and Mesna tablets.
- Most people having Cyclophosphamide with Mesna do not develop. any problems with their bladder, but your doctor may want to test your urine for the presence of blood using a 'dipstick' or
- If you notice that you have blood in the urine, you must tell your doctor straight away as they may need to stop giving you . Cvclophospha
- Cancer medicines and radiation therapy can increase the risk of you developing other cancers; this can be a number of years after your reatment has stopped. Cyclophosphamide has an increased risk of causing cancer in the area of your bladder.
- Cyclophosphamide can cause damage to your heart or affect the rhythm of it beating. This increases with higher doses of Cyclophosphamide, if you are being treated with radiation or other chemotherapy medicines or if you are elderly. Your doctor will monitor your heart closely during treatment
- Cyclophosphamide can cause inflammation or scarring in your lungs. This can occur more than six months after your treatment. If you start having difficulty breathing tell your doctor straight away.
- Cyclophosphamide can have life threatening effects on your liver. If you have sudden weight gain, liver pain and jaundice tell your doctor straight away.
- Hair thinning or baldness can occur. Your hair should grow back normally though it may be different in texture or colour.
- Cyclophosphamide can make you feel sick or be sick. This can last for about 24 hours after taking Cyclophosphamide. You may need to be given medicines to stop feeling or being sick. Ask your doctor about this

#### Using other medicines and treatments

Tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines you have bought yourself. In particular, tell them about the following medicines or treatments as they may not work well with Cyclophosphamide

The following medicines can reduce how effective Cyclophosphamide

- aprepitant (used to prevent being sick)
- bupropion (an anti-depressant)
- busulfan, thiotepa (used to treat cancer)
- ciprofloxacin, chloramphenicol (used to treat bacterial infections)
- fluconazole, itraconazole (used to treat fungal infections)
- Prasugrel (used to thin the blood)
- Sulfonamides, such as sulfadiazine, sulfasalazine, sulfamethoxazole (used to treat bacterial infections)

The following medicines can increase the toxicity of Cvclophosphamide:

- allopurinol (used to treat gout)
- azathioprine (used to reduce the activity of the immune system)
- chloral hydrate (used to treat insomnia)
- cimetidine (used to reduce stomach acid)
- disulfiram (used to treat alcoholism)
- glyceraldehyde (used to treat warts)
- protease inhibitors (used to treat viruses)
- ondansetron (used to prevent being sick)
- medicines that increase liver enzymes such as
- rifampicin (used to treat bacterial infections)
- carbamazepine, phenobarbital, phenytoin (used to treat epilepsy)
- St. John's wort (a herbal remedy for mild depression)
- Corticosteroids (used to treat inflammation)
- medicines that can increase the toxic effects on your blood cells and immunity
- ACE inhibitors (used to treat high blood pressure)
- natalizumah (used to treat multiple sclerosis)
- paclitaxel (used to treat cancer)
- thiazide diuretics such as hydrochlorothiazide or chlortalidone (used to treat high blood pressure or water retention) zidovudine (used to treat viruses
- Clozapine (used to treat symptoms of some psychiatric disorders

etanercept (used to treat rheumatoid arthritis)

• coumarins such as warfarin (used to thin the blood)

digoxin, B-acetyldigoxin (used to treat heart conditions)

Cyclophosphamide with food and drink

Pregnancy, breast-feeding and fertility

contraceptive. Ask your doctor for advice.

tamoxifen (used to treat breast cancer)

• bupropion (used to help stop smoking)

vaccines

Cyclophosphamide.

trying to become pregnant

your doctor for advice.

before your treatment starts

- medicines that can increase the toxic effects on your heart anthracyclines such as bleomycin, doxorubicin, epirubicin,
- mitomycin (used to treat cancer) - cytarabine , pentostatin, trastuzumab (used to treat cancer)
- radiation in the area of your heart • medicines that can increase the toxic effects on your lungs
- amiodarone (used to treat irregular heart beat) - G-CSF, GM-CSF hormones (used to increase white blood cell numbers after chemotherapy)
- medicines that can increase the toxic effects on your kidneys - amphotericin B (used to treat fungal infections)
- Indomethacin (used to treat pain and inflammation) Other medicines that can affect or be affected by Cyclophosphamide

• metronidazole (used to treat bacterial or protozoal infections)

• cyclosporine (used to reduce the activity of the immune system)

• verapamil (used to treat high blood pressure, angina or irregular

Drinking alcohol can increase the nausea and vomiting caused by

Do not become pregnant while taking Cyclophosphamide. This is

Men or women should not try to have a child during or for at

because it can cause miscarriage or damage your unborn baby. Tell

your doctor if you are pregnant, think you might be pregnant or are

least 6 to 12 months after treatment. You should use an effective

future. Talk to your doctor about freezing sperm samples or eggs

Do not breast-feed while being treated with Cyclophosphamide. Ask

Cyclophosphamide can affect your ability to have children in the

succinvlcholine (used to relax muscles during medical procedures)

#### Driving or using machines

Some of the side effects of treatment with Cyclophosphamide might affect your ability to drive and use machines safely. Your doctor will decide if it is safe for you to do so.

### What to do if you see a different doctor, or have to go to hospital

If you see any other doctor or have to go to hospital for any reason, tell them what medicines you are taking. Do not take any other medicines unless your doctor knows you are taking Cyclophosphamid

# 3 How to take Cyclophosphamide

#### Taking this medicine

- Cyclophosphamide Tablets are to be taken by mouth. Do not chew
- If you are also having Mesna, your doctor will tell you how much you need to drin You should take your tablets with enough liquid to make them easy
- to swallow. • Cyclophosphamide is often given with other anti-cancer drugs or
- radiotherapy

# The usual dose

- Your doctor will decide how much of the medicine you need and when you should take it.
- The amount of Cyclophosphamide you will need to take depends on: the type of illness you have how big you are (a combination of your height and weight)
- vour general health
- whether you are being given other anti-cancer drugs or having radiotherapy
- The usual dose is between 100 mg (2 tablets) and 300 mg (6 tablets) per day. You can take all of one day's tablets togethe but you should try to take them about the same time each day. preferably in the morning. If you are not sure how to take your tablets, ask your doctor or pharmacist

Cyclophosphamide is usually taken for several days in a row as a course, and then there is a break (a period when no tablets are taken) before the next course. Sometimes you may need to take different numbers of tablets on alternate days, for instance, 3 tablets one day and 4 the next

- Your doctor may need to change the amount of medicine you are given and monitor you more closely if you
- have problems with your liver or kidneys
- vou are elderly.

#### If you forget to take Cyclophosphamide

If you forget to take your Cyclophosphamide:

- you should take them as soon as you remember, if it is on the same day. If you have forgotten to take a whole day's tablets, then you should talk to your doctor
- Never take more tablets in one day than you were meant to - so never take two days worth of tablets on the same day in order to 'catch up'.

#### If you take too much Cyclophosphamide

In the event of an overdose, or if a child swallows any of your tablets, talk to your doctor or local hospital emergency department immediately. Hospital admission for special treatment may be needed

#### 4 Possible side effects

Like all medicines. Cyclophosphamide can cause side effects. although not everybody gets them. Side effects can sometimes occur after ending the treatment. The following side effects may happen with this medicine.

## Tell your doctor straight away, and go to hospital immediately if you notice any of the following serious side effects:

- allergic reactions, signs of this would be shortness of breath, wheezing, rash, itching or swelling of the face and lips (hypersensitivity). Severe allergic reactions could lead to difficulty n breathing or shock, with a possible fatal outcome (anaphylactic shock, anaphylactic/ anaphylactoid reaction)
- getting bruises without knocking yourself, or bleeding from your gums. This may be a sign that the platelet levels in your blood are aettina too low
- a lowering of your white blood cell count your doctor will check this during your treatment. It will not cause any signs, but you will be more likely to get infections. If you think you have an infection (a high temperature, feeling cold and shivery, or hot and sweaty, or any signs of infection such as a cough, or stinging on passing water) you may need antibiotics to fight infections because you blood count is lower than usual

- blood in your urine, pain while passing urine, or less urine being passed (hemorrhagic cystitis, haematuria
- inflammation of your intestines or bowel which may resulting in bleeding (hemorrhagic enterocolitis)
- fits (convulsions)
- life threatening conditions which cause rash, ulcers, sore throat, fever, conjunctivitis, separation of skin layers (toxic epidermal necrolysis, Stevens-Johnson syndrome), Swelling, numbness, red lumps and peeling of skin on the hands and feet (Palmar-plantar erythrodysesthesia syndrome
- If the threatening decrease in the abilities of your kidney to adequately remove toxins and waste products from the blood (kidney failure). These changes to the tissues within your kidney can prevent them from working correctly, and induce kidney failure (renal tubular necrosis, renal tubular disorder)
- pneumonia. Signs of this could be chest pain when you breather or cough, confusion, coughing, fever, sweating and chills, fatigue, shortness of breath, nausea, vomiting or diarrhoea
- severe infection spreading through the blood which may lead to a dangerous drop in blood pressure with a possible fatal outcome (sepsis, shock)
- effects on the brain (encephalopathy), signs of this can be problems in thinking or concentrating, reduced alertness, changes in personality, tiredness, fits, muscle twitching, and shaking
- a syndrome called reversible posterior leukoencephalopathy syndrome, which can cause swelling of the brain, headache, confusion, fits and loss of sight
- heart attack (myocardial infarction)
- decrease in your hearts ability to pump enough blood around your body which may be life threatening (cardiogenic shock, heart failure or cardiac arrest)
- life-threatening decrease of your lungs ability to transfer oxygen in to your blood (respiratory failure)
- a build-up of toxins in the body due to liver failure (hepatotoxicity). This may affect the brain causing confusion, reduced consciousnes or coma (hepatic encephalopathy)

# Tell your doctor straight away, if you notice any of the following serious side effects:

- haemolytic uremic syndrome a condition causing abnormal break down of the red blood cells, decreased numbers of platelets in the blood and kidney failure
- cancer of your blood (leukaemia)
- cancer of the bone marrow (myelodysplastic syndrome)
- swelling of the brain due to too much water in your blood (water intoxication). Signs of this can be headache, changes in personality or behaviour, confusion, drowsiness formation of small blood clots in your blood vessels disrupting the
- normal blood flow around your body (disseminated intravascular coagulation)
- blood clot in the lungs which causes chest pain and breathlessness (pulmonary embo
- blood clot, usually in a leg, which causes pain swelling or redness (venous thrombosis) Iow blood levels of sodium which can cause tiredness and
- confusion, muscle twitching, fits and coma (hyponatremia) • tummy discomfort or severe tummy and back pain, this may be
- caused by inflammation of the pancreas (acute pancreatitis) • high blood sugar levels which can cause thirst, tiredness and
- irritability (hyperglycaemia) • low blood sugar levels which can cause confusion and sweating
- hypoglycaemia effects on the spinal cord (Myelonathy) which can cause numbres
- weakness and tingling in the hands, loss of motor skills
- disease of the heart muscle (cardiomyopathy); inflammation of the tissues in or around your heart (myocarditis, pericarditis); build up of fluid in the sac around your heart (pericardial effusion). Increased pressure from this fluid can stop the heart filling properly (cardiac tamponade); abnormal ECG heart tracing (Electrocardiogram QT prolonged) - These could be considered causes of arrythmia
- changes in your heart rhythm (arrhythmia) which may be noticeable
- irregular heart heat (fibrillation)
- faster heart beat (tachycardia), which may be life threatening (ventricular tachycardia
- slower heart beat (bradycardia)
- blood clot in the lungs which causes chest pain and breathlessness (pulmonary veno-occlusive disease
- scarring of the lungs which causes shortness of breath (pulmonary) fibrosis)
- conditions causing inflammation of the lungs which can cause breathlessness, cough and raised temperature or scarring of the lungs (pneumonitis, acute respiratory distress syndrome, obliterativ bronchiolitis, organizing pneumonia, alveolitis allergic)
- fluid in or around the lungs (pulmonary oedema, pleural effusion) increased blood pressure in the lungs which can cause shortness of breath, fatique, cough, angina, fainting, peripheral oedema (pulmonary hypertension)

• abnormal muscle breakdown which can lead to kidney problems (rhabdomvolvsis)

colour or temperature

blocked or runny nose

cough

iaundice

• shortness of breath (dyspnea)

• pain at the back of your throat

increased liver size (hepatomegaly)

and shortness of breath (ascites)

• dark red raised itchy rash (urticaria)

excessive sweating (hyperhidrosis)

• swelling of the face

• itching (pruritus)

muscle spasms

• premature labour

womb

swelling

this medicine.

month.

pharmacist.

Yellow Card Scheme

www.mhra.gov.uk/yellowcard

5 How to store Cyclophosphamide

Keep this medicine out of the sight and reach of children

• Do not store above 25°C. Store in the original container.

Do not use Cyclophosphamide after the expiry date which is stated

Medicines should not be disposed of via wastewater or household

waste. If you have any medicine left over, take it back to your

on the label after EXP. The expiry date refers to the last day of that

gastroenteritis

general physical deterioration

pain, weakness, tiredness

Reporting of side effects

injection site reaction.

(haemorrhagic ureteritis)

death of the cells and tissues (necrosis)

treatment (radiation recall dermatitis)

• difficulty in breathing or wheezing (bronchospasm)

decrease levels of oxygen in your body (hypoxia)

• yellowing of the skin or whites of the eyes (jaundice)

iaundice, weight loss and malaise (hepatitis)

• blockage of the small veins in your liver (veno-occlusive liver)

• conditions causing inflammation of the liver which can cause

disruption of the formation of bile by the liver which can cause

itchiness, jaundice, pale coloured stools, dark urine (cholestasis)

• a build-up of fluid in the abdomen causing swelling of the tummy

redness and blistering of the skin appearing months or years after

• itchy, red rash which can develop in to sores (erythema multiforme)

serious illness which causes thickening of the skin and the

connective tissue in your internal organs (scleroderma)

• glucose in the urine (nephrogenic diabetes insipidus)

Inflammation of the urethra which causes pain and bleeding

• decrease in the size of the bladder (bladder contracture)

• increase in the levels of creatinine or urea nitrogen in your blood.

• infertility. Sperm production in men and egg production in women

may be reduced or stop. In some cases this can be permanent

• use in young patients may result in some impairments of future

• reduction in growth, deformity or death of a foetus while in the

• life threatening failure of multiple organs such as heart, lungs,

• flu-like symptoms such as headache, fever, chills, joint and muscle

If you get any side effects, talk to your doctor, nurse or pharmacist.

This includes any possible side effects not listed in this leaflet. You

can also report side effects directly (see details below). By reporting

side effects you can help provide more information on the safety of

• toxic effects on the foetus such as myelosuppression and

kidney, liver (see symptoms throughout section 4)

reduced frequency of menstrual periods (oligomenorrhea)

changes to the cells in the lining of your bladder

Your doctor will do blood tests to test for these

decrease in testicle size (testicular atrophy)

• decrease in the hormone oestrogen in the blood

increase in the hormone gonadotrophin in the blood

muscle pain (myalgia) or joint pain (arthralgia)

disease) which can cause weight gain, increased liver size, pain and

#### Other possible side effects, listed by frequency, may he

Very common: may effect more than 1 in 10 people

- reduction in the effectiveness of your immune system
- hair loss (alopecia)
- pain and difficultly passing urine (cystitis)
- very pale, lethargic and tired. This may be a sign of low red blood cells (anaemia). Usually, no treatment is required, your body will eventually replace the red blood cells. If you are very anaemic, you may need a blood transfusio
- Common: may effect up to 1 in 10 people
- increased risk and severity of bacterial, fungal, viral, protozoal or parasitic infections due to the effect of cyclophosphamide on your immune system
- reactivation of infections you have had before (latent infections)
- increased levels of certain proteins produced by your liver called enzymes. Your doctor will do blood tests to test for these
- inflammation of the bladder lining which causes pain, bleeding blood in the urine, reduced urine flow (haemorrhagic cystitis)
- inflammation of the linings of your body cavities (mucosal inflammation)

#### Uncommon: may effect up to 1 in 100 people

- Ioss of appetite (anorexia)
  - reddening of the skin (flushing) which may be accompanied by feeling hot or sweating (hot flushing)
- Rare: may effect up to 1 in 1.000 people
- secondary tumours in various parts of the body, often in the area of damage to the kidneys by toxins in the blood (toxic nephropathy) the bladder
- dehvdration
- dizziness
- blurring, reduction or loss of sight
- changes in colour of your fingernails and skin. inflammation of this skin which may cause rash, blisters, itching, sores, oozing and scarring (dermatitis)
- absence of menstrual periods (amenorrhea)
- chest pain
- Very rare: may effect up to 1 in 10,000 people
- increase in the release of antidiuretic hormone from the pituitary gland. This affects the kidneys causing the low levels of sodium in your blood (hypernatremia) and water retention
- accumulation of fluid in the body (water retention), which may been seen as fluid beneath the skin or swelling in you limbs
- feeling sick and being sick (nausea, vomiting)
- constinution or diarrhoea

• eve oedema (swelling)

bleeding (enteritis, cecitis)

set of nerves (polyneuropathy)

sation (neuralgia

shaking (tremor)

- ulcers in the lining of your digestive system (mucosal ulceration)
- inflammation of the lining of your mouth including ulcers (stomatitis)

Unknown: frequency cannot be estimated from the available data

• inflammation of your intestines or bowel which may resulting in

inflammation which causes abdominal pain or diarrhoea (colitis)

swelling of the glands in your neck (parotid gland inflammation).

• a disorder of the nerves which can cause weakness, tingling or

• tingling or numbness, often in the hands or feet (paresthesia)

changes in your sense of taste (dysgeusia) or loss of taste

changes in your sense of smell (parosmia)

inflammation of the blood vessels (vasculitis)

increased tear formation (lacrimation)

• deafness or hearing impairment

ringing in the ears (tinnitus)

• changes in your sense of touch (dysesthesia) or loss of sensation

reduced blood supply to your hands and feet (peripheral ischemia).

This may cause pain, weakness, numbness, ulcers, changes in ski

numbness (peripheral neuropathy). This could be in more than one

• pain from your nerves, which can also feel like an aching or burning

• bleeding in your stomach or intestines (gastrointestinal)

• changes to your metabolism caused by the breakdown of the dying

- confusion
- ulceration or scaring (fibrosis) of the bladder

inflammation of the eye (conjunctivitis)

cancer cells (Tumour lysis syndrome)

# 6 Contents of the pack and other information

### What Cyclophosphamide contains

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The active substance is Cyclophosphamide and each tablet contains 50 mg.

Other ingredients are: maize starch, lactose monohydrate, calcium hydrogen phosphate, talc, magnesium stearate, gelatine, glycerol, sucrose, titanium dioxide (E171), calcium carbonate, macrogol, colloidal anhydrous silica, povidone, carmellose sodium, polysorbate 20, montan glycol wax.

# What Cyclophosphamide looks like and contents of the pack

Cyclophosphamide Tablets are white, round, coated tablets with a white core. There are 10 tablets in a blister strip and 10 blister strips in a box.

# Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is: Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom Send all enquiries to this address. Cyclophosphamide is manufactured by: Baxter Oncology GmbH Kantstrasse 2, 33790 Halle/Westfalen Germany

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For information about Cyclophosphamide or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345. Baxter is a trademark of Baxter International Inc

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