

# [Medicine name]<sup>®</sup> *(if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

## Consumer Medicine Information

Consumer Name  
Consumer Address  
Consumer Address

## Date of Dispensing

Pharmacist Name  
Pharmacist Address  
Pharmacist Address

### What is in this leaflet<sup>1</sup>

This leaflet answers some common questions about [Medicine name].

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 [Medicine name] against the benefits they expect it will 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.

***Note: The statements in this core document are optional. Some may not be appropriate for a given product. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Second Edition of the Usability Guidelines wherever possible.***

### What [Medicine name] is used for

*Include information on the expected effects of using [Medicine name], the therapeutic indications (that is, what it is used for), the pharmacotherapeutic group and how it works etc. Choose the indication(s) below as appropriate to your product(s):*

[Medicine name] is used to treat (primary indication<sup>2</sup>). It may also be used to treat (secondary indications).

#### *Indications<sup>3</sup>:*

- prostate cancer.
- cancer of the testes.
- breast cancer.
- breast cancer in women who are post-menopausal (that is, women who no longer have their menstrual periods, either naturally due to their age or because they have had a hysterectomy).
- ovarian cancer.
- cervical cancer.
- cancer of the uterus (womb).
- cancer of the female reproductive organs.
- a type of cancer called sarcoma.
- rhabdomyosarcoma, a cancer of skeletal muscle.

<sup>2</sup> *If your product is indicated for many cancers, you may like to write "[Medicine name] is used to treat some types of cancer" instead of listing all the indicated cancers.*

<sup>3</sup> *If the indication is for metastatic disease, consider writing "... which has spread to other parts of the body" after the indicated cancer.*

- Ewing's sarcoma, which is a type of bone cancer.
- bone cancer.
- Letterer-Siwe disease.
- Kaposi's sarcoma in people who have acquired immunodeficiency syndrome (AIDS). Kaposi's sarcoma is a type of cancer which mainly affects the skin. It may also affect the stomach, intestines and lungs.
- (hairy cell, acute lymphoblastic, acute lymphocytic, myeloid, acute promyelocytic, chronic myelogenous) leukaemia.<sup>4</sup>
- cancer of the brain and/or spinal cord.
- neuroblastoma, a cancer of nerves and the adrenal glands.
- Wilms' tumour, a cancer of the kidneys.
- cancer of the pancreas.
- multiple myeloma, a cancer of the blood.
- a type of cancer called lymphoblastoma
- (Hodgkin's, non-Hodgkin's, lymphocytic, histiocytic) lymphoma, a cancer of the lymph glands.
- mycosis fungoides, a cancer of the lymph glands which affects your skin
- basal cell carcinoma and malignant melanoma, which are types of skin cancer.
- some types of lung cancer.
- cancer of the bladder.
- bowel cancer.
- rheumatoid arthritis, a condition with painful, swollen joints.

<sup>4</sup> *Unless the patient would be told the type of leukaemia, consider just writing "leukaemia" or "some types of leukaemia"*

<sup>1</sup> *Depending on the length of your CMI, consider using a table of contents (see Second Edition of the Usability Guidelines).*

- diseases of the immune system, which affect your body's ability to fight disease.
- psoriasis, a stubborn skin condition with thickened patches of red skin, often with silvery scales.
- solar keratosis, a skin condition with hard, thick patches of skin.
- genital warts.
- fibroids of your uterus (womb). Fibroids are growths in your uterus which are not cancer.
- endometriosis. Endometriosis is a condition where the cells of your uterus (womb) grow outside your uterus, causing pain, discomfort or bleeding.
- Hepatitis B and/or Hepatitis C.
- help prevent transplant rejection.

[Medicine name] belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

[Medicine name] works by / is thought to work by killing cancer cells and/or stopping cancer cells from growing and multiplying.

[Medicine name] helps boost your immune system to help your body fight cancer.

[Medicine name] is specially developed to target cancer cells rather than normal, healthy cells.

[Medicine name] works by stopping cells from growing and multiplying.

Your doctor may have prescribed [Medicine name] for another reason. Ask your doctor if you have any questions about why [Medicine name] has been prescribed for you.

*If second line therapy:*

You have probably taken another medicine to treat your (*indicated condition*). However, your doctor has now recommended you should be given [Medicine Name].

*If combination therapy:*

[Medicine name] is often / may be used in combination with other medicines to treat cancer.

*If any adjunct therapy:*

[Medicine name] is usually given with a (steroid medicine / other medicines) to help prevent side effects.

[Medicine name] is not addictive.

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

*Use in children statement: (if not a contraindication)*

[Medicine Name] is not recommended for use in children (under the age of x), as there is not enough information on its effects in children / in this age group.

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### **Before you take [Medicine name]**

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or

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### **Before you use [Medicine name]**

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or

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### **Before you are given [Medicine name]**

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***When you must not take it  
When you must not use it  
When you must not be given it***

**Do not take/use/have [Medicine name] if you have an allergy to [Medicine name] or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to [Medicine name] may include:

*List symptoms as per your PI. If your PI doesn't state specific hypersensitivity symptoms, you may wish to consider the following:*

- 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
- back pain

Your doctor may give you a small test dose to see how you react to [Medicine name].

**Do not take/use/have [Medicine name] if you have, or have had, any of the following medical conditions:**

- liver problems (*severe liver impairment, liver disease, liver dysfunction*)
- heart problems, including a heart attack (*myocardial insufficiency, myocardial infarction*)
- kidney problems (*renal impairment, severe renal disorders*)
- hearing problems (*hearing disorders*)
- inflammation of your pancreas (*pancreatitis*)
- stomach ulcer (*peptic ulcer*)
- ulcerative colitis, a condition where your colon (large bowel) is inflamed and has ulcers (*ulcerative colitis*)
- tuberculosis (TB) or a positive BCG reaction (*tuberculosis*)
- urinary tract infection (*urinary tract infection*)
- some forms of Charcot-Marie-Tooth disease
- a disease of the nervous system (*neuropathy*)
- condition of the blood with a reduced number of red / white blood cells / platelets (*leucopenia, low neutrophil counts, severe anaemia, thrombocytopenia, leucopenia*)
- ??? (*coexistent or suspected infectious granuloma*) – **Robyn to check and suggest consumer terms**
- poor health due to a lack of proper nutrition (*poor nutritional status*)
- lowered immunity due to diseases including HIV / AIDS or cancer (*primary or acquired immunodeficiency, immunocompromised patients*)
- lowered immunity due to treatment with medicines such

as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy) (*immunocompromised patients*)

- list any other contraindicated medical conditions, as per PI

**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 take/use/have [Medicine name] if you have already received the full, long-term dose of [Medicine name] or another anthracycline medicine.**

**Do not take/use/have [Medicine name] if you have had surgery in the last x days.**

**Do not take/use/have [Medicine name] if you** -traumatic catheterisation ??? – Robin to suggest consumer terms

**Do not take/use/have [Medicine name] if you are receiving radiation therapy or any other medicines which lower your immune system.**

*If pregnancy a contraindication:*

**Do not take/use/have [Medicine name] if you are pregnant or intend to become pregnant.**

Like most medicines used to treat cancer, [Medicine name] is not recommended for use during pregnancy / in the first 3 months of pregnancy, unless you and your doctor have discussed the risks and benefits involved.

or:

**Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.**

Like most cytotoxic medicines [Medicine Name] is not recommended for use during pregnancy. If there is any need to consider [Medicine name] during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

**Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are using [Medicine Name] or shortly after you have stopped using [Medicine Name].**

[Medicine name] may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are using [Medicine name] and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

or

[Medicine name] may affect your developing baby if you take it during pregnancy.

**Do not breastfeed while taking [Medicine name].**

[Medicine name] passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

**Do not take/use/have [Medicine name] after the expiry date (EXP)<sup>5</sup> printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take/use/have [Medicine name] if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking/using/having [Medicine name], talk to your doctor or pharmacist.**

**Before you start to take it  
Before you use it  
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 (*hepatitis, hepatic dysfunction, hepatic impairment*)
- yellowing of the skin and/or eyes (*jaundice*)
- kidney problems (*renal dysfunction, acute uric acid nephropathy*)
- heart problems, including a heart attack (*cardiac dysfunction, previous heart attack*)
- lung problems, including asthma (*pre-existing lung disease, ascites, pleiral effusion, asthma*)
- thyroid problems (*thyroid disease*)
- peripheral neuropathy, which you may notice as numbness or weakness in your arms and legs (*peripheral neuropathy*)
- persistent fever
- frequent vomiting
- frequent urination (*small bladder capacity*)
- difficulty passing urine
- constipation (*difficulty having bowel motions*)
- ulcerative colitis, a condition where your colon (large bowel) is inflamed and has ulcers (*ulcerative colitis*)
- stomach ulcer (peptic ulcer)
- disease of the nerves and muscles (*pre-existing neuromuscular disease*)
- problems with your blood vessels, or with blood clots
- blood disorder with a reduced number of red / white blood cells / platelets (*myelosuppression*)
- loss of a lot of weight (*severe weight loss*)
- skin ulcers (*skin ulcers*)
- high uric acid levels in your blood, which may cause gout (*hyperuricaemia*)
- rheumatoid arthritis, a condition with painful, swollen joints, and other diseases of your immune system.
- diabetes (*diabetes*)
- high blood pressure (*hypertension*)
- convulsions, fits or seizures (*history of convulsions*)

<sup>5</sup> Only include 'EXP' if that is the abbreviation used on your packaging.

- mental illnesses such as schizophrenia, mania and certain types of depression (*psychiatric illnesses, mental disorders*)
- recent operation to remove your spleen, kidneys or adrenal glands
- lowered immunity due to diseases including HIV / AIDS or cancer (*primary or acquired immunodeficiency, immunocompromised patients*)
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy) (*immunocompromised patients*)
- *list any other medical conditions which are precautions, as per PI*

*If pregnancy is a precaution:*

**Tell your doctor if you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of using [Medicine name] during pregnancy.

*or:*

Like most medicines used to treat cancer, [Medicine name] is not recommended to be used during pregnancy. (If there is a need to consider [Medicine name] during your pregnancy, your doctor will discuss with you the benefits and risks of using it.)

Both men and women taking [Medicine name] and their partners must use a reliable method of contraception for x months before, during and x months after receiving [Medicine name].

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breast-feed while taking [Medicine name], as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

*Any other precautions, as per PI.*

**If you have not told your doctor about any of the above, tell them before you start taking/using/having [Medicine name].**

**Taking other medicines**

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

Some medicines and [Medicine name] may interfere with each other. These include:

- other medicines used to treat cancer<sup>6</sup>, radiation therapy or any other treatment which lowers your immune system
- methotrexate
- medicines used to prevent blood clots, including warfarin and heparin
- diuretics, also called water or fluid tablets
- phenytoin, phenobarbitone and valproic acid, medicines used to treat epilepsy
- theophylline, a medicine used to treat asthma
- some medicines used to treat bacterial infections, including ...
- ketoconazole and itraconazole, medicines used to treat fungal infections
- pyrimethamine, a medicine used to treat malaria
- zidovudine, a medicine used to treat AIDS
- medicines used to treat tuberculosis
- some glucocorticoids, including dexamethasone and prednisolone
- allopurinol and probenecid, medicines used to treat gout
- amiodarone, a medicine used to treat irregular heart beats
- non-steroidal anti-inflammatory drugs (NSAIDs) and salicylates, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- methoxalen, a medicine used to treat a skin condition called vitiligo

- nifedipine and propranolol, medicines used to treat high blood pressure and angina
- prochlorperazine, a medicine used to treat nausea or vomiting
- sulfonyleurea medicines, some medicines used to treat diabetes
- medicines containing the female sex hormone progestogen, such as some oral contraceptives
- general anaesthetics, medicines used to put you to sleep during an operation
- nitrous oxide, a gas (inhaled) anaesthetic
- some vitamins such as folic acid, Vitamin A and multi-vitamins
- laxatives, medicines used to treat constipation
- ultraviolet (UV) light, which is used to treat some skin conditions
- some vaccines (ask your doctor)
- alcohol
- *List any other drug interactions, as per PI*

These medicines may be affected by [Medicine name], or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use/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 taking/using/having [Medicine name].

*For oral medicines:*

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## How to take [Medicine name]

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*This information will be product specific, consistent with the approved PI. The following subheadings and order of information is suggested, but will depend upon the particular product and the amount of information to be given.*

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

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<sup>6</sup> if used in combination therapy, you may need to specify which ones

Your doctor or pharmacist will tell you how many tablets/capsules you will need to take the time between doses and the length of time to take [Medicine Name]. This depends on your condition and your weight and whether or not you are taking any other medicines.

**Follow all directions given to you by your doctor or pharmacist carefully.**

Your dose may change from time to time depending on how you respond. To help you take the correct dose, ask your doctor or pharmacist to complete the chart on Page x of this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

**How much to take**

*Include dosage ranges, usual doses for each indication or patient group etc.*

**How to take it**

**Swallow [Medicine name] with a glass of water.**

*or:*

**Swallow [Medicine name] whole with a full glass of water.**

**Do not chew the capsules.**

The capsules have a special coating to stop them dissolving until they have passed through the stomach into the intestines where they work. Chewing them destroys the coating.

**When to take it**

**Take [Medicine name] at about the same time each day.**

Taking your tablets/capsules at the same time each day will have the best effect. It will also help you remember when to take the tablets/capsules.

It does not matter if you take [Medicine name] before or after food. However, taking [Medicine name] with food may help prevent any stomach upsets.

*or:*

[Medicine name]

**Take [Medicine name] on an empty stomach, for example, 1 hour before food or 2 hours after food.**

Food can interfere with the absorption of [Medicine name].

**How long to take it**

**Continue taking your medicine for as long as your doctor tells you.**

Your doctor will tell you when your treatment should be stopped.

[Medicine Name] may be used either as a short course or on an ongoing basis. If you are not sure how long you should take the tablets, ask your doctor or pharmacist.

**If you forget to take it**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

**If you have forgotten to take a dose of [Medicine name], contact your doctor.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**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 pharmacist or the Poisons Information Centre (telephone 13 11 26)<sup>7</sup>, or go to**

<sup>7</sup> Consider including the relevant New Zealand telephone numbers here.

**Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention<sup>8</sup>.

If you take too much [Medicine name], you may feel ..... *(list symptoms in PI)*

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**How to use [Medicine name]**

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*For topical medicines:*

**Where to use it**

*(include information from PI)*

**Do not put it on open wounds or injuries.**

**Do not put it inside the mouth or vagina.**

**Be careful not to get it in your eyes.**

If this happens, rinse your eyes with clean water and tell your doctor or pharmacist.

**Never swallow this medicine.**

**How to use it**

**Using your fingers/applicator, rub a thin layer of [Medicine name] on the affected area of skin x times each day, unless you have been given other instructions by your doctor.**

The amount you will need will depend on the size of the painful or swollen area.

Take care when applying the solution near your eyes, nose or mouth.

Wash your hands after rubbing in [Medicine name], unless they are the area being treated.

**When to use it**

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<sup>8</sup> The reference to accident and emergency and urgent medical attention could be left out, depending on the type of product.

*Amend as necessary, depending on dosing intervals etc.*

Use [Medicine name] at the same time every day.

### **How long to use it**

Continue using your medicine for as long as your doctor tells you.

Your doctor will tell you when your treatment should be stopped.

### **If you forget to use it**

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

If you have forgotten to apply a dose of [Medicine name], contact your doctor.

If you are not sure what to do, ask your doctor or pharmacist.

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

### **If you use too much (overdose)**

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26)<sup>9</sup>, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention<sup>10</sup>.

*For injections, infusions or intravesical administration:*

<sup>9</sup> Consider including the relevant New Zealand telephone numbers here.

<sup>10</sup> The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

[Medicine name]

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## **How [Medicine name] is given**

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*Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor.*

### **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 other chemotherapy medicines you are being given.

[Medicine name] may be given alone or in combination with other drugs.

Several courses of [Medicine Name] therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of [Medicine name] you receive.

### **How it is given**

*For injections:*

[Medicine name] is given as a slow injection into a vein. [Medicine name] must only be given by a doctor or nurse.

*or:*

[Medicine name] is given as an injection, usually into your upper arm muscle by a doctor or trained nurse.

*or:*

[Medicine name] is given as an injection under the skin (subcutaneously), usually near your stomach.

*or:*

[Medicine name] is usually given as an injection into your veins (intravenously).

*For infusions:*

[Medicine name] is given as an infusion (drip) into your veins, over x minutes/hours.

*For intravesical administration:*

[Medicine name] is given through a rubber tube (called a catheter) into your bladder.

### **How long it is given**

[Medicine name] is usually given ... (specify usual length of time of one cycle – time on treatment and time between treatments). This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

## **Overdose**

**As [Medicine name] 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 [Medicine name], tell your doctor immediately or go to Accident and Emergency at your nearest hospital.**

You may need urgent medical attention<sup>11</sup>.

Symptoms of a [Medicine Name] 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 using [Medicine name]**

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### **Things you must do**

**Be sure to 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

<sup>11</sup> The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

time to check on your progress and detect any unwanted side effects.

*For cyclical therapy*

### **Keep follow up appointments with your doctor.**

It is important to have your follow-up doses/cycles/infusions of [Medicine name] at the appropriate times to get the best effects from your treatments.

### **Intravesical use and urination – Robyn to come up with wording.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking/using/having [Medicine name].**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking/using/having [Medicine name].**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking/using/having [Medicine name].**

**If you become pregnant while taking/using/having [Medicine name], tell your doctor.**

[Medicine name] 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.

*For cytotoxics if appropriate:*

Your body breaks down [Medicine name] and uses it to fight cancer, the breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

*Any other instructions, as per PI.*

### **Things you must not do**

**Do not give [Medicine name] to anyone else, even if they have the same condition as you.**

**Do not take/use/have [Medicine name] to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not open the capsules. If a capsule is damaged, avoid contact with your skin and eyes. If you accidentally touch or inhale the powder, carefully wash the affected area with water. Avoid inhaling the powder.**

**Do not drink alcohol while taking [Medicine name].**

You may feel flushed or get headaches (*disulfuram reaction*).

**Do not to take more than your doctor has prescribed.**

High doses of [Medicine name] may be associated with a serious blood disorder.

*Any other instructions, as per PI.*

### **Things to be careful of**

**Be careful driving or operating machinery until you know how [Medicine name] affects you.**

As with other *therapeutic class* medicines, [Medicine name] may cause dizziness, light-headedness, tiredness, drowsiness (*as per PI*) in some people. Make sure you know how you react to [Medicine name] 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.

*Any other instructions, as per PI.*

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## **Side effects**

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*The side effects for a particular product will depend on the PI and the company's disclosure policy.*

*The following side effects have been listed according to severity. Select those side effects applicable to your product.*

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking/using/having [Medicine name].**

Like other medicines that treat cancer, [Medicine name] may have unwanted side effects, some of which may be serious. You may

need medical treatment if you get some of the side effects.

*Alternative for adjunct therapy:*

[Medicine name] may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. 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:**

- *list as per PI (see List 1)*<sup>12</sup>

These are the more common side effects of [Medicine name].

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

- *list as per PI (see List 2)*

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:**

- *list as per PI (see List 3)*

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. (Optional)**

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<sup>12</sup> List medical terms in brackets after the consumer terminology. The medical terms are not to go into the CMI; rather, they are there to help the CMI writer choose applicable wording for adverse events listed in their PI.

You may not experience any of them.<sup>13</sup>

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

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## After using [Medicine name]

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*This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.*

### Storage

**Keep your tablets/capsules/ suppositories/eye drops /ointment etc. in the pack/bottle until it is time to take/use/have them.**

If you take/use/have the tablets/capsules/ suppositories/eye drops /ointment etc. out of the pack/bottle they will not keep well.

**Keep your tablets/capsules/ suppositories/eyedrops/ointment etc. in a cool dry place where the temperature stays below XX°C.**

**Do not store [Medicine name] or any other medicine in the bathroom or near a sink.**

**Do not leave it on a window sill or in the car on hot days.** Heat and dampness can destroy some medicines.

**Keep it 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.

*Injections only:*

### Storage

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<sup>13</sup> Consider placing this statement at the beginning of this section.

[Medicine name] 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 XX°C.

*The following are alternative statements which should be considered if patients are required to purchase and store their medications prior to treatment.*

[Medicine name] should be stored in a cool dry place where the temperature stays below XX°C.

Store [Medicine name] in the refrigerator (2-8°C). Do not freeze.

Do not leave [Medicine name] in the car.

Protect [Medicine name] from light.

### Disposal

**If your doctor or pharmacist tells you to stop taking/using/having [Medicine name] or the tablets/capsules/suppositories/eye drops/ointment has/have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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*This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.*

**What it looks like**  
*Include any tablet scoring etc.*  
**Ingredients**

Active ingredients:

- *list actives*

Other ingredients

- *list excipients*

*If appropriate:*

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

*Where Australian Food Standard codes exist, these could follow each Australian Approved name.*

***Manufacturer/Distributor/  
Supplier***

*Include:*

- *Name and address of sponsor*
- *AUST R number*
- *Date of preparation*

*A dosing chart may be appended as a separate page if appropriate for your product.*