

Core CMI for the Hormonal Antineoplastic Agents (*text in italics is instructional for the CMI writer only*)

[Medicine name][®] *(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 leaflet¹

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/being given [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

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

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 appropriate indication(s) and mechanism(s) of action for your product:

Indications:

[Medicine name] is used to treat (primary indication). It may also be used to treat (secondary indications).

List of indications:²

- 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).
- cancer of the endometrium (the lining of the uterus or womb).
- cancer of the kidneys.
- prostate cancer.
- breast cancer in men.
- 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

² Insert the appropriate primary and secondary indications in the paragraph above from this list. If your product has several indications, you may wish to list them. If so, use dot points, not arrows. If your product has many antineoplastic indications, you may like to write "[Medicine name] is used to treat some types of cancer" instead.

- outside your uterus, causing pain, discomfort or bleeding.
- overactivity of the adrenal gland in people who have Cushing's syndrome. It is usually used for a short time only, until other treatment such as surgery can be given.
- AIDS patients for loss of appetite or severe weight loss.
- abnormal vaginal bleeding.
- absence of menstrual periods not due to pregnancy.
- as a contraceptive agent. Each injection helps prevent pregnancy for 3 months.

Mechanism of action - for the anti-oestrogens:

[Medicine name] is an anti-oestrogen medicine. Oestrogen is a natural female sex hormone. In some types of breast cancer, oestrogen can help the cancer cells to grow. By blocking oestrogen, [Medicine name] may slow or stop the growth of cancer.

Mechanism of action - for megestrol acetate:

[Medicine name] is used to treat the symptoms of breast cancer. The growth of some breast cancers is stimulated by the female hormones oestrogen and progesterone. [Medicine name] contains the medicine megestrol acetate, which is similar in structure to progesterone and can block the stimulating effect of progesterone on the growth of breast cancer.

Mechanism of action - for the anti-androgens:

[Medicine name] is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow. By blocking these hormones, [Medicine name] may slow or stop the growth of cancer.

Mechanism of action - for the LHRH agonists:

[Medicine name] works by blocking the production of some sex hormones such as oestrogen and androgens (e.g. testosterone). Oestrogen is a natural female sex hormone. Androgens are natural male sex hormones.

In some types of cancer, these hormones may help the cancer cells to grow. By blocking these hormones, [Medicine name] may slow or stop the growth of cancer.

Who should not take it:

[Medicine name] should only be taken by men. It should not be taken by women or children.

[Medicine name] is not recommended for use in children.

If second line therapy:

You have probably taken another medicine to treat your (*indicated condition*). However, your doctor has now decided to treat you with [Medicine name] instead.

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 to help prevent side effects.

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

Your doctor may have prescribed [Medicine name] for another reason.

[Medicine name]

[Medicine name] is not addictive. This medicine is available only with a doctor's prescription.

Before you take [Medicine name]

or

Before you are given [Medicine name]

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

Do not take [Medicine name] if you have an allergy to:

- [generic name], the active ingredient in [Medicine name]
- any of the other ingredients of [Medicine name] listed at the end of this leaflet
- other anti-oestrogen/anti-androgen medicines
- *any others as per PI*

Symptoms of an allergic reaction to [Medicine name] 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.

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

- liver problems (*severe liver failure, markedly impaired liver function*)
- difficulty breathing (*respiratory insufficiency*)
- high blood pressure which is not controlled (*severe uncontrolled hypertension*)
- overgrowth in the lining of your uterus (womb) (*endometrial hyperplasia*)
- a rare blood disorder called porphyria (*inducible porphyria*)
- history of blood clots or stroke (*thrombophlebitis, thromboembolic disorders, cerebral apoplexy*)
- *list any other contraindicated medical conditions, as per PI*

Do not take [Medicine name] if you have any of the following symptoms, until your doctor has examined you to find the cause of your symptoms:

- blood in your urine
- unusual vaginal bleeding that is not connected with a menstrual period
- changes in your breasts such as lumps or bleeding nipples, or if you have had a mammogram that showed breast changes

Do not take [Medicine name] if you are still having menstrual periods (i.e. you have not yet reached the menopause).

Do not take [Medicine name] if you have taken another anti-androgen medicine that did not work.

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

[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 give [Medicine name] to a child, unless directed by the child's doctor.

There is no/not enough experience with the use of [Medicine name] in children.

Any other contraindications as per PI.

Do not take [Medicine name] after the expiry date (EXP)³ printed on the pack.

Do not take [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.

³ Only include 'EXP' if that is the abbreviation used on your packaging.

If you are not sure whether you should start taking [Medicine name], talk to your doctor.

Before you start to take it **Before you are given it**

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Precautions:

Tell your doctor if you have or have had any medical conditions, especially the following:

- your cancer has spread to your backbone (*metastatic vertebral lesions*)
- liver problems (*hepatic insufficiency, cirrhosis*)
- kidney problems (*renal insufficiency*)
- heart problems, including angina (*non-compensated cardiac insufficiency, angina*)
- high blood pressure (hypertension) (*hypertension*)
- migraine headaches
- unusual or irregular vaginal bleeding or “spotting”
- blood clots
- stroke
- a low white blood cell count, which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers (*leucopenia*)
- a low blood platelet count, which you may notice as bleeding or bruising more easily than normal (*thrombocytopenia*)
- osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines)
- diabetes (that is not controlled), or a family history of diabetes
- breast cancer, or a family history of breast cancer
- changes in your breasts such as lumps or bleeding nipples, or if you have had a mammogram that showed breast changes
- asthma

- epilepsy
- depression
- high calcium levels in your blood, which you may notice as loss of appetite, nausea, vomiting, constipation and stomach pain (*hypercalcaemia*)
- *list any other medical conditions which are precautions, as per PI*

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

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

Any other precautions, as per PI.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking 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 cancer⁴
- medicines used to prevent blood clots, including warfarin
- diuretics, also called water or fluid tablets
- phenytoin, phenobarbitone and carbamazepine, medicines used to treat epilepsy
- propranolol, a medicine used to treat high blood pressure or other heart conditions
- diazepam, a medicine used to treat anxiety
- theophylline, a medicine used to treat asthma
- some medicines used to treat bacterial infections, including erythromycin and clarithromycin
- some medicines used to treat fungal infections, including

⁴ if used in combination therapy, you may need to specify which ones

- ketoconazole (*or other examples, as per PI*)
- medicines used to treat diabetes (except insulin)
- a hormone medicine called medroxyprogesterone
- medicines which contain oestrogen, such as oral contraceptives and medicines used in hormone replacement therapy (HRT)
- some glucocorticoids, including dexamethasone and prednisone
- bromocriptine
- 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 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 [Medicine name].

For oral medicines:

How to take [Medicine name]

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.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. (This depends on your condition and whether or not you are taking any other medicines.)

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

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary. Include any special precautions etc.

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

When to take it

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary. Include time to take medicine with respect to food, dosing intervals, etc.

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

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

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

How long to take it

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Continue taking your medicine for as long as your doctor or pharmacist tells you.

[Medicine name] helps control your condition, but does not cure it. Therefore you must take [Medicine name] every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take it

[Medicine name]

If it is almost time for your next dose (within x hours), 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 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)⁵, or go to 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 attention⁶.

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

For injectable medicines:

How [Medicine name] is given

⁵ Consider including the relevant New Zealand telephone numbers here.

⁶ The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

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

Dosage ranges, usual doses for each indication etc as per PI.

How it is given

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

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

How often it is given

[Medicine name] is usually given every x weeks/months. Make sure you keep a diary of when your doses are due.

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 attention⁷.

While you are using [Medicine name]

Things you must do

Following are some examples from the Usability Guidelines. Choose

⁷ The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

whichever is appropriate or amend as necessary.

If you are being treated for *indication* and experience any of the following symptoms within the first x weeks of treatment, tell your doctor:

- bone pain (*bone pain*)
- difficulty passing urine (*urinary obstruction*)
- tingling or numbness in your hands or feet (*spinal cord compression*)
- *list any other side effects of flare reaction, as per PI*

These symptoms usually only happen with the first treatment with [Medicine name]. You should not experience them with further treatments.

If you become pregnant while taking [Medicine name], tell your doctor.

If you are using oral contraceptives, talk to your doctor.

[Medicine name] may decrease the effectiveness of some birth control pills. Your doctor may advise you to use an additional method of contraception while taking [Medicine name].

If you have any abnormal vaginal bleeding while taking [Medicine name], tell your doctor.

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 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.

If you feel that your medicine is not helping your condition, talk to your doctor.

[Medicine name]

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

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

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 [Medicine name] to treat any other complaints unless your doctor tells you to.

Do not stop taking [Medicine name], or lower the dosage, without checking with your doctor.

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 category* 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.

If [Medicine name] makes you feel dizzy or light-headed, be careful when getting up from a sitting or lying position.

These are signs of low blood pressure.

Any other instructions, as per PI.

Side effects

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 or pharmacist as soon as possible if you do not feel well while you are taking [Medicine name].

[Medicine name] helps most people with *indication*, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects.

If you get any side effects, do not stop taking [Medicine name] without first talking to your doctor or pharmacist.

Ask your doctor or pharmacist to answer any questions you may have.

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

These are very serious side effects. You may need urgent medical attention or hospitalisation. (These side effects are very rare.)

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (*anaphylaxis*)
- chest pain
- coughing up blood
- sudden, severe headache (*thromboembolism, stroke*)
- sharp, stabbing pain or swelling in your lower leg muscle (calf muscle)
- swelling and redness along a vein which is extremely tender when touched (*phlebitis, thrombophlebitis*)

- symptoms of blood problems such as frequent infections, fever, severe chills, sore throat or mouth ulcers, or bleeding or bruising more easily than normal (*thrombocytopenia, agranulocytosis*)
- severe blisters, or bleeding in the lips, eyes, nose, mouth or genitals (*Stevens Johnson Syndrome*)
- *list any other side effects, as per PI⁸*

Tell your doctor as soon as possible if you notice any of the following.

These side effects may be serious. You may need medical attention. (Serious side effects are rare.)

- problems with your eyesight
- difficulty speaking
- difficulty breathing (*shortness or breath, asthma*)
- (tingling, numbness or) weakness in your arms or legs (*carpal tunnel syndrome, spinal cord compression, peripheral neuropathy*)
- severe back pain (*spinal cord compression*)
- swelling in your hands, feet or ankles (*oedema*)
- pain in your lower stomach
- unusual vaginal bleeding or discharge (*endometrial cancer*)
- lumps in your breast (*breast cancer*)
- unusual secretion of breast milk
- bleeding nipples
- yellowing of the skin and/or eyes or dark coloured urine (*hepatitis, cholestasis, cholestatic jaundice*)
- flaking or peeling of the skin (*exfoliative dermatitis*)
- symptoms of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale (*anaemia*)
- weight gain with a rounded (moon-shaped) face and high

blood pressure (*Cushing's Syndrome*)

- symptoms of diabetes such as excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine (*hyperglycaemia, diabetes mellitus*)
- frequent urination (*urinary frequency, nocturia*)
- urgent need to pass urine (*urinary urgency*)
- loss of control of your bladder (incontinence) (*incontinence*)
- difficulty or pain when passing urine (*urinary obstruction*)
- high calcium levels in your blood, which you may notice as loss of appetite, nausea, vomiting, constipation and stomach pain (*hypercalcaemia*)
- *list any other side effects, as per PI*

Tell your doctor if you notice any of the following and they worry you.

These side effects are usually mild.

or:

These are the more common side effects of [Medicine name]. (Mostly these are mild and short-lived.)

- pain, swelling or redness at the injection site
- dry eyes
- dry mouth
- vaginal itching or dryness
- cough
- ringing or buzzing in your ears (*tinnitus*)
- mild skin problems such as rash, itching, hives, dry skin or acne
- sweating and body odour
- hot flushes
- fever and/or chills (*hyperpyrexia*)
- headache
- feeling the cold and having a slow heart rate (*hypothyroidism*)
- high blood pressure (*hypertension*)
- dizziness or light-headedness (*hypotension*)
- spinning sensation (*vertigo*)

- unusual tiredness, weakness sleepiness, drowsiness or lack of energy (*somnolence, fatigue, asthenia, fatigue*)
- difficulty sleeping (*insomnia, sleeping disturbances*)
- nervousness, depression or other mood changes
- confusion
- unsteadiness when walking (*ataxia*)
- fainting
- shaking or tremors (*tremor*)
- leg cramps
- mild muscle, joint or back pain (*arthralgia, myalgia*)
- change in your sexual drive (*changes in libido*)
- inability to get or maintain an erection (impotence) (*impotence*)
- changes in your menstrual periods
- changes in breast size in men or women (*breast atrophy, breast enlargement, gynaecomastia*)
- breast swelling and/or tenderness in men or women
- changes in testicular size (*testicular atrophy*)
- hair loss or thinning (*alopecia*)
- excessive hairiness, especially in women (*hirsutism, masculinisation*)
- loss of appetite (*anorexia*)
- changes in appetite
- weight changes
- indigestion or stomach upsets (*dyspepsia, abdominal pain*)
- nausea and/or vomiting
- diarrhoea
- constipation
- flatulence (wind) (*flatulence*)
- *list any other side effects, as per PI*

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may happen in some people. Some of these side effects (for example, *as per PI*.) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

⁸ Medical terms are listed in italics and 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.⁹

After using [Medicine name]

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

Storage

For injections only:

[Medicine name] is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store [Medicine name]:

For all formulations:

Keep your medicine 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.

Keep [Medicine name] in the original container until it is time to take it / for it to be given.

If you take your medicine out of the original container, it will not keep well.

Keep your medicine in a cool dry place where the temperature stays below [x]°C.

Do not store [Medicine name] in the refrigerator.

Do not freeze [Medicine name]. Freezing destroys the medicine.

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.

Disposal

If your doctor tells you to stop treatment with [Medicine name] or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

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*

⁹ Consider placing this statement at the beginning of this section.