

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking CYTOTEC?

CYTOTEC contains the active ingredient misoprostol. CYTOTEC can help make your stomach produce less acid, and it helps your stomach protect itself against damage from acid and certain other substances, such as NSAIDs. CYTOTEC can be used also to treat acute ulcers in the stomach and small intestine. CYTOTEC can also be used to prevent bleeding in the stomach or upper intestine in hospital patients after surgery.

For more information, see Section [1. Why am I taking CYTOTEC?](#) in the full CMI.

2. What should I know before I take CYTOTEC?

Do not take if you have ever had an allergic reaction to misoprostol or any of the ingredients listed at the end of the CMI.

Do not take CYTOTEC if pregnant, planning to be pregnant or if there is any chance you may be pregnant, or are breastfeeding.

Talk to your doctor if you have any other medical conditions, or take any other medicines.

For more information, see Section [2. What should I know before I take CYTOTEC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CYTOTEC and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CYTOTEC?

- Follow doctor's instructions for how to take CYTOTEC.
- CYTOTEC is best taken with food.

More instructions can be found in Section [4. How do I take CYTOTEC?](#) in the full CMI.

5. What should I know while taking CYTOTEC?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using CYTOTEC.• If an antacid is needed for stomach pain, use one which does not contain magnesium. Aluminium-containing antacids may be used when needed for relief of pain. Ask your doctor or pharmacist for advice if necessary.
Things you should not do	<ul style="list-style-type: none">• Do not take CYTOTEC if pregnant or planning to be pregnant.• Do not take CYTOTEC if you are breast feeding.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how CYTOTEC affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place (where the temperature stays below 25°C) away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using CYTOTEC?](#) in the full CMI.

6. Are there any side effects?

Common side effects include stomach pains, diarrhoea, nausea, vomiting, wind or heartburn. Anaphylaxis is a serious side effect.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CYTOTEC®

Active ingredient(s): *misoprostol*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I taking CYTOTEC?](#)
- [2. What should I know before I take CYTOTEC?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CYTOTEC?](#)
- [5. What should I know while taking CYTOTEC?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CYTOTEC?

CYTOTEC contains the active ingredient misoprostol.

Misoprostol is very similar to a group of substances called prostaglandins, which occur naturally in the stomach and other parts of the body.

When the amount of these natural prostaglandins is lower than normal, there is a risk that ulcers may occur in the stomach or duodenum (the first part of the small intestine).

This reduction in prostaglandins is often a side effect of medicines known as non-Steroidal anti-inflammatory Medicines (NSAIDs).

CYTOTEC makes your stomach produce less acid. CYTOTEC can also help prevent ulcers by strengthening the stomach lining

CYTOTEC is used:

- To treat acute ulcers in the stomach (gastric ulcers), or in the first part of the small intestine (duodenal ulcers).
- To prevent development of stomach ulcers in patients at high risk of developing ulcers, which may be caused by anti-inflammatory medicines known as NSAIDs.
- To prevent stress-induced bleeding in the stomach or upper intestine in hospital patients after surgery.

Your doctor, however, may prescribe CYTOTEC for another purpose.

Ask your doctor if you have any questions about why CYTOTEC has been prescribed for you.

There is no evidence that CYTOTEC is addictive.

2. What should I know before I take CYTOTEC?

Warnings

Do not take CYTOTEC:

1. If you are allergic to misoprostol (or another prostaglandin medicine), or any of the ingredients listed at the end of this leaflet. If you have an allergic reaction

you may get a skin rash, difficulty in breathing, hayfever or faintness. Always check the ingredients to make sure you can use this medicine.

2. If you are pregnant, or there is a possibility you may be pregnant, or if you intend to become pregnant.

Tell your doctor if you become pregnant while you are taking CYTOTEC - see *Pregnancy and Breastfeeding* below.

3. After the expiry date (EXP) printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you use it after the expiry date.

4. If the packaging shows signs of tampering.
5. To treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Check with your doctor if you:

- have any other medical conditions especially:
 - epilepsy
 - asthma
 - diseases of the heart or blood vessels.
 - bowel disease
- take any medicines for any other condition including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop
- You are allergic to any other medicines or any foods, dyes or preservatives

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take CYTOTEC if you are pregnant or intend to become pregnant.

The effects of CYTOTEC may be harmful to a developing baby (fetus).

CYTOTEC must not be used by pregnant women as it may cause miscarriage, and this could lead to potentially dangerous bleeding, hospitalisation, surgery, infertility or death. You should not become pregnant while taking CYTOTEC.

If it is possible for you to become pregnant, you should use adequate contraception while you are taking CYTOTEC. Examples of adequate contraception include oral contraceptives ("the pill") or intra-uterine devices (IUDs).

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

CYTOTEC passes into breast milk, therefore it is not recommended that you take CYTOTEC if you are breast feeding.

Use in children

The effects of CYTOTEC have only been studied in adults, and there is no specific information comparing its use in children with use in adults.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, or if you are not sure about any medicines, including any vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

If an antacid is needed, please see [Section 5. What should I know while taking CYTOTEC?](#) for more information.

4. How do I take CYTOTEC?

How much to take / use

- The usual dosage of CYTOTEC is one tablet two, three or four times a day.
- CYTOTEC is best taken with food. Do not take CYTOTEC on an empty stomach.
- Follow your doctor's instructions exactly on how much CYTOTEC to take, and for how long to take it.
- If you are taking an NSAID, CYTOTEC may be prescribed for as long as you are taking the NSAID, whether or not you have stomach pain or other symptoms of ulcers. Some ulcers are painless, particularly those caused by NSAIDs.

If you forget to take CYTOTEC

CYTOTEC should be used regularly at the same time each day.

If you miss a dose of CYTOTEC, take it as soon as possible. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much CYTOTEC

If you think that you have used too much CYTOTEC, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre Australia (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Signs that may indicate an overdose of CYTOTEC include: sedation (feeling sleepy), shaking, fits, shortness of breath, stomach pains, diarrhoea, contraction of the uterus (womb), heart palpitations, low blood pressure or slow heart beat.

5. What should I know while taking CYTOTEC?

Things you should do

Take CYTOTEC exactly as your doctor has prescribed.

Tell all doctors, dentist and pharmacists who are treating you that you are taking CYTOTEC.

If an antacid is needed for stomach pain, use one which does not contain magnesium. Aluminium-containing antacids may be used when needed for relief of pain. Ask your doctor or pharmacist for advice if necessary.

Things you should not do

Stop taking CYTOTEC if you become pregnant or you think you may be pregnant.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CYTOTEC affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place (where the temperature stays below 25°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat or moisture may cause CYTOTEC tablets to deteriorate.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Keep your tablets in their blister until it is time to take them. If you take the tablets out of the blister they may not keep well.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Gastrointestinal symptoms: <ul style="list-style-type: none">• Stomach pains• Diarrhoea• Nausea• Vomiting• Wind (flatulence)• Indigestion (heartburn)• Constipation Other: <ul style="list-style-type: none">• Headaches• Chills• Fever• Dizziness	Speak to your doctor if you have any of these common side effects and they worry you. <u>Regarding stomach pains or diarrhoea:</u> If either of such occur, they usually settle down within a week or two. If you take CYTOTEC with food, you will have less chance of getting diarrhoea (or

Common side effects	What to do
<ul style="list-style-type: none"> Menstrual (period) problems such as spotting or heavier than normal bleeding 	<p>it will not be as bad, if you do get it). If you use an antacid (to reduce acid in your stomach), ask the pharmacist to recommend one which contains aluminium, since antacids which contain magnesium may make diarrhoea worse. Tell your doctor if stomach pains or diarrhoea are severe or do not stop after a week.</p>

(inactive ingredients)	sodium starch glycollate castor oil-hydrogenated
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Do not take this medicine if you are allergic to any of these ingredients.

What CYTOTEC looks like

CYTOTEC tablets are scored, white, hexagonal tablets, marked on one side with SEARLE/1461 (AUST R 63983).

Packs contain 120 tablets.

Who distributes CYTOTEC

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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Serious side effects

Serious side effects	What to do
<p>Anaphylaxis:</p> <ul style="list-style-type: none"> Trouble breathing Chest tightness Faintness Changes in skin colour <p>These may be signs of a severe allergic reaction which may be life-threatening.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Check with your doctor as soon as possible if you have any problems while taking CYTOTEC even if you think they are not connected with the medicine or are not listed in this leaflet.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CYTOTEC contains

Active ingredient (main ingredient)	200 micrograms of misoprostol
Other ingredients	cellulose-microcrystalline hypromellose