

Package leaflet: Information for the user

Cytotec® 200 microgram Tablets

Misoprostol

Read all of this leaflet carefully before you start using 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 yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Cytotec is and what it is used for

- Cytotec tablets contain misoprostol which is similar to a chemical substance called 'prostaglandin' which your body produces naturally. Prostaglandins are produced in the stomach and intestine and help to protect the lining. Cytotec belongs to a group of medicines known as 'anti-ulcer agents'.
- The Cytotec tablets may help prevent you getting ulcers in your stomach or the part it empties into, called the duodenum. These ulcers could be caused by taking non-steroidal anti inflammatory drugs (NSAIDs) like diclofenac and naproxen. The way NSAIDs work means they reduce the amount of prostaglandins in your stomach and intestine. This can cause indigestion and lead to ulcers forming. The Cytotec tablets will replace these prostaglandins and help to protect your stomach and intestine, so you can continue getting benefit from your NSAID. Cytotec also reduces acid and increases bicarbonate in your stomach secretions.
- Cytotec can also be used to heal existing ulcers.

2. What you need to know before you take Cytotec

Cytotec may not be suitable for everyone. Please read the following list carefully to see if any of these apply to you. Consult your doctor if you are not sure.

Do not take Cytotec

- if you are allergic to misoprostol or any of the other ingredients of this medicine (listed in section 6), or other prostaglandin medicines.
- If you are a woman of childbearing age and you are not using an effective contraceptive method to avoid becoming pregnant (see Section 'Pregnancy' for further information).
- if you are pregnant or trying to become pregnant or do not have a negative pregnancy test because it may cause a miscarriage, premature birth or birth defects (see section 'Pregnancy' for further information).
- if you are breastfeeding (as this may give your baby diarrhoea).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cytotec. Tell your doctor if you have any of the following conditions to help him or her decide if Cytotec is suitable for you:

- if you are pregnant or plan to become pregnant (see subsection “pregnancy” below). Due to the risk for the foetus, your treatment with Cytotec must be discontinued immediately.
- if you are a woman of childbearing age (see subsection “pregnancy” below). Due to the risk for the foetus, it is important to use effective contraception while you are taking Cytotec.
- heart disease.
- low or high blood pressure, or any disease of the blood vessels.
- inflammatory bowel disease.
- prone to dehydration.

If you are a younger woman who has not yet gone through the menopause, your doctor will have only prescribed Cytotec if he is satisfied you are at high risk of developing ulcers from your NSAID medicine.

Other medicines and Cytotec

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You can take Cytotec with most medicines without any problems. If you use an antacid (something to reduce acid in the stomach) you should avoid antacids with magnesium in them as these may make diarrhoea worse.

If you are taking any medicines for a heart condition, please consult your doctor.

Use with NSAIDs in rare cases can result in swelling of feet or hands and an increase in liver enzymes.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Cytotec with food, drink and alcohol

Please refer to section 3.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Cytotec if you are pregnant or plan to become pregnant. Your doctor will make you aware of the risks if you do become pregnant as Cytotec may cause a miscarriage, premature birth or birth defects. Pregnancies exposed to misoprostol during the first trimester have been associated with approximately a 3-fold increased risk of birth defects, in particular facial paralysis, limb defects, cerebral and cranial anomalies. If you are exposed to Cytotec during pregnancy, talk with your doctor. If you decide to continue with the pregnancy, careful pre-natal monitoring and repeated ultrasound examinations, with a special attention to the limbs and head must be carried out.

If you are a younger woman who has not yet gone through the menopause, your doctor will have only prescribed Cytotec if he is satisfied you are at high risk of developing ulcers from your NSAID medicine.

Cytotec can cause a miscarriage or damage to your womb, so it is very important to use reliable contraception while taking this medicine. The risk of damage to your womb is greater in the later stages of pregnancy, and if you have had a previous Caesarean delivery or have given birth to five

or more children. If you want to try for a baby, tell your doctor as you will have to stop taking Cytotec and use a different treatment.

Cytotec should not be taken by pregnant women and in women planning a pregnancy.

Do not breast-feed while taking Cytotec.

Driving and using machines

Dizziness has been reported after taking Cytotec. Be cautious when driving or operating machinery until you know how the medicine affects you.

Cytotec contains sodium

Cytotec contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Cytotec

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should take Cytotec with food.

Cytotec is suitable only for adults aged 18 years and over.

To heal ulcers in your stomach or duodenum

You should normally take two 200 microgram Cytotec tablets twice a day with food. Alternatively you can take one Cytotec tablet four times a day, at regular intervals with food.

Treatment will usually last for 4 weeks, but may be extended up to 8 weeks.

If your ulcers are not completely healed after this period, further treatment may be given.

To prevent ulcers when taking NSAID medicines

You should usually take one 200 microgram tablet, two, three or four times a day. Your doctor will adjust your dose to suit you.

You will need to continue to take Cytotec as long as is needed to protect your stomach or gut, and must keep taking the tablets until your doctor advises you to stop.

If you take more Cytotec than you should

If you take too many tablets, contact your doctor or accident and emergency department straight away.

If you forget to take Cytotec

If you forget to take a dose of your tablets, take them as soon as you remember. But if it is almost time for your next dose, do not take the tablet(s) you have missed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. Most of these don't happen very often, are not serious and will often wear off after a while. If you are worried about any side effects, then talk to your doctor.

Stop taking the tablets and get emergency medical help immediately if you have any of the symptoms below which could represent an allergic reaction:

- swelling of the face, lips, tongue or throat (angioedema)
- difficulty in breathing
- swelling of the extremities (hands and feet)

If you get any of the following symptoms, tell your doctor immediately:

- prolonged heavy or painful bleeding
- abnormal contractions of the womb

The following side effects have been reported with Cytotec:

Very common: may affect more than 1 in 10 people

- skin rashes
- diarrhoea

Diarrhoea is the most common problem and is occasionally severe. You have less chance of getting diarrhoea if you take Cytotec with food. If you use an antacid (something to reduce acid in the stomach) you should avoid antacids with magnesium in them as these may make diarrhoea worse. Your pharmacist can help you choose a suitable antacid.

Common: may affect up to 1 in 10 people

- dizziness
- headache
- stomach pain
- constipation
- wind
- indigestion
- feeling or being sick
- birth defects (foetal malformations). If you become pregnant during treatment, stop taking Cytotec immediately and seek medical advice

Uncommon: may affect up to 1 in 100 people

- vaginal bleeding (some women may have vaginal bleeding even though they have gone through the menopause)
- bleeding between periods
- irregular periods
- uterine cramps
- fever

Rare: may affect up to 1 in 1,000 people

- tearing of the womb (uterine rupture) after intake of prostaglandins in the second or third trimester of pregnancy, mainly in women with previous deliveries of a child or with a scar of a caesarean section. Seek immediate medical attention
- heavy periods (menorrhagia)
- painful periods (dysmenorrhoea)

Not known: frequency cannot be estimated from the available data

- allergic reactions, including swelling of the hands and feet, face, lips, tongue or throat and which may lead to significant difficulty breathing
- abnormal uterine contractions
- amniotic fluid (the fluid which surrounds the foetus during pregnancy) entering the mother's bloodstream, causing an allergic reaction
- foetal death

- incomplete miscarriage
- premature birth
- placenta remaining in the womb after birth, termination or miscarriage
- perforation (penetrating damage of the wall) of the uterus
- uterine bleeding
- chills

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cytotec

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister strip after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the blister in the outer carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cytotec contains

- The active substance is misoprostol. Each Cytotec tablet contains 200 micrograms (mcg) of misoprostol.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate, hydrogenated castor oil, and hypromellose (E464).

What Cytotec looks like and contents of the pack

Cytotec tablets are white to off white hexagonal tablets scored on both sides and engraved 'SEARLE 1461' on one side. The tablets are packed in aluminium foil blisters in cartons containing 56, 60, 112, 120 or 140 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer

Piramal Healthcare UK Limited
Whalton Road, Morpeth

Northumberland
NE61 3YA
United Kingdom

Company Contact Address

For further information on your medicine please contact Medical Information at the following address: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS; Tel 01304 616161.

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