

Package leaflet: Information for the patient

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

1. What Cytotec is and what it is used for
2. What you need to know before you take Cytotec
3. How to take Cytotec
4. Possible side effects
5. How to store Cytotec
6. Contents of the pack and other information

1. What Cytotec is and what it is used for

- Cytotec contains 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. Misoprostol belongs to a group of medicines known as 'anti-ulcer agents'.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Cytotec

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 on '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 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.

- 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.
- have heart disease
- have low or high blood pressure
- have any disease of the blood circulation or blood vessels
- have suffered a stroke
- are prone to dehydration
- have inflammatory bowel disease

Take special care with Cytotec if you have a medical condition which causes bouts of abdominal pain or diarrhoea (due to an inflamed bowel). You must **tell your doctor immediately** if you notice that your stools contain blood or have a dark, tarry appearance or if you vomit blood.

In certain conditions your doctor may need to perform further investigations to diagnose this and exclude the possibility of cancer of the bowel.

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

Children and adolescents

The use of Cytotec in children has not yet been evaluated.

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 take Cytotec with drugs such as aspirin, or ibuprofen (Non Steroidal Anti inflammatory drugs), this can cause in rare cases, an increase in the levels of liver enzymes in the blood. These liver enzymes are known as transaminases. They can also cause swelling of the body tissues, usually in the lower limbs. The swelling of body tissues is due to an accumulation of fluid (peripheral oedema).

If you take Cytotec with the drug propranolol, (used to treat angina, high blood pressure, heart attack), this can increase the concentrations of the drug propranolol, in your blood stream.

Cytotec with food and drink

Please refer to section 3, How to take Cytotec.

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 they are 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 (see section 4, 'Possible side effects', for further information).

Do not breast-feed while taking Cytotec as this may give your baby diarrhoea.

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 hydrogenated castor oil

Cytotec contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

To heal ulcers in your stomach or duodenum

To heal ulcers in your stomach or duodenum you should normally take two 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

To prevent ulcers when taking NSAID medicines you should usually take one Cytotec tablet, two, three or four times a day. Your doctor will adjust your dose to suit you. You should take your Cytotec tablet with food.

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.

Elderly

The usual dosage may be used.

In patient with kidney and liver disorders

No change in dosage is necessary.

Use in children and adolescents

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

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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cytotec

Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first.

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.

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

- anaphylactic reaction (this involves swelling of the face, lips, tongue or throat (angioedema) which may cause great difficulty breathing; swelling of the extremities (hands and feet)).

The following side effects are specific to pregnancy:

- abnormal contractions of the womb
- bleeding from the womb
- tearing of the tissues in the womb
- placenta remaining in the womb after birth or miscarriage
- amniotic fluid (the fluid which surrounds the baby when pregnant) entering the mother's bloodstream causing amniotic fluid embolism
- incomplete miscarriage and premature birth
- foetal death and birth defects

The following side effects have been reported with Cytotec:

Very common: may affect more than 1 in 10 people

- skin rash
- diarrhoea

You have less chance of getting diarrhoea if you take Cytotec with food. If you use an antacid (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
- indigestion
- wind
- nausea
- vomiting
- 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

- period problems including heavy bleeding or bleeding between periods

- some older women may have vaginal bleeding even though they have gone through the menopause.
- cramping of the womb
- high temperature

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

- abnormal menstrual blood loss
- severe menstrual pains
- Tearing of the womb (uterine rupture) after administration 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 urgent medical attention.

Not known: frequency cannot be estimated from the available data

- 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 HPRA Pharmacovigilance. Website: www.hpra.ie. 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 Cytotec after the expiry date which is stated on the carton or blister strip after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package to protect from moisture.

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 tablet contains 200 micrograms (mcg) of misoprostol. The other ingredients are: microcrystalline cellulose, sodium starch glycolate, hydrogenated castor oil (See section 2 **Cytotec contains hydrogenated castor oil**) and hypromellose (E464).

What Cytotec looks like and contents of the pack

Cytotec tablets are white to off white flat hexagonal shaped tablets scored on both sides with 'SEARLE' over '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 (Ireland)

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park
Citywest Business Park
Dublin 24
Ireland

Manufacturer

Piramal Pharma Solutions (Dutch) B.V.
Bargelaan 200
Leiden, 2333 CW
Netherlands

Company Contact Address

For further information on your medicine, please contact Medical Information at the following address:

Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland

Telephone: 1 800 633 363

This leaflet was last revised in 06/2024.

Ref: CZ 16_0 IE