Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Cytotec® 200 mcg tablets

Each tablet contains:
misoprostol 200 mcg

Inactive ingredients and allergens: see section 2 "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for children and adolescents below the age of 18.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- Treatment of duodenal and gastric ulcers.
- Treatment and prevention of non-steroidal anti-inflammatory drugs (NSAID) induced ulcers lesions, erosions, while NSAID therapy continues.
- Use in conjunction with Mifepristone subject to the approval of a pregnancy termination committee, according to the Israeli penal law 1977.
- First-trimester pregnancy failure:
  Use is intended for emptying the uterus in states of first trimester pregnancy failure, including: presentation of a pregnancy sac in the uterus with no fetal echo, missed abortion (until week 11+6 and a fetus of 40 mm in length) or incomplete abortion.
  The preparation is to be used after location of the pregnancy sac in the uterus has been proven and the diagnosis of pregnancy failure is certain. The preparation can be used for this purpose in an ambulatory setting. The route of administration and dosage will be similar to the use of Cytotec® in pregnancy termination after using Mifegyne. Informed consent and medical surveillance are required.
- Softening and dilation of the cervix for performing intrauterine procedures, such as curettage, hysteroscopy, intrauterine device insertion and others, according to clinical judgment. The preparation can be used for this purpose in an ambulatory setting.

  The route of administration – vaginal, sublingual, buccal, oral or rectal, and the dosage will be determined according to the decision of the attending doctor.

Therapeutic group:
Cytotec® contains misoprostol, which is similar to the chemical component called "prostaglandin" which your body produces naturally. Prostaglandins are produced in the stomach and intestine and help to protect the gastrointestinal lining (mucosal layer). Cytotec® belongs to the group of medicines known as 'anti-ulcer' drugs.
Cytotec® tablets can help to prevent ulcers in the stomach or in the part it empties into, called: the duodenum. The ulcers could be caused by taking non-steroidal anti-inflammatory drugs (NSAIDs), which reduce the amount of prostaglandins in the stomach and intestine, this may lead to indigestion and formation of ulcers. Cytotec® tablets will replace these prostaglandins and help to protect the stomach and intestine, so that it is possible to continue and take NSAIDs. Cytotec® also reduces the acid level and increases bicarbonate in gastric secretions. In addition, Cytotec® can be used to heal existing ulcers.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

x you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine or to other medicines containing prostaglandin analogs (see section 6).
x you are a woman of childbearing age and you are not using an effective contraceptive method to avoid becoming pregnant (see section 'Pregnancy and breastfeeding' for further information), you are pregnant, trying to become pregnant or do not have a negative pregnancy test because the treatment may cause a miscarriage, premature birth or birth defects in the newborn (see section 'Pregnancy and breastfeeding' for further information), except cases of combined treatment with mifepristone to terminate a pregnancy - subject to approval of a pregnancy termination committee, according to the Penal Law 1977.
x you are breastfeeding (the treatment may cause your baby to suffer from diarrhea)

Special warnings regarding use of the medicine
Before treatment with Cytotec®, tell your doctor if:
- you are pregnant or planning to become pregnant (see section 'Pregnancy, breastfeeding and fertility'). Due to the risk to the fetus, your treatment must be stopped immediately.
- you are a woman of childbearing age (see section 'Pregnancy, breastfeeding and fertility) who may become pregnant during the period of treatment with the medicine. Due to the risk to the fetus, it is important to use effective contraception during treatment with the medicine.
- you are suffering from a heart disease, high or low blood pressure or a disease in blood vessels.
- you are suffering from inflammatory bowel disease.
- you are suffering from impaired kidney (renal) function.
- you are prone to dehydration.

If you are a young pre-menopausal woman, your doctor will prescribe Cytotec® to you only if he is certain that you are at high risk of developing ulcers due to using a non-steroidal anti-inflammatory drug.

Children and adolescents
Cytotec® is suitable for use only in adults above the age of 18.

Tests and follow-up
A blood test to exclude pregnancy should be conducted prior to starting treatment in women who may become pregnant during treatment with the medicine.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Particularly if you are taking:
- Antacids containing magnesium, since the combination may lead to exacerbation of diarrhea.
- Medicines from the non-steroidal anti-inflammatory drugs (NSAIDs) group, since in rare cases, the combination can cause swelling of the feet or hands and increase in liver enzymes.
- Medicines for treating heart diseases.

Using this medicine and food
The medicine should be taken with food.

Pregnancy, breastfeeding, and fertility
Do not use the medicine if you are pregnant, planning to become pregnant or breastfeeding (except cases of combined treatment with mifepristone to terminate a pregnancy - subject to approval of a pregnancy termination committee, according to the Penal Law 1977).

Your doctor will inform you of the risks if you become pregnant, since Cytotec® may cause a miscarriage, premature birth or birth defects. Pregnancies exposed to this medicine during the first trimester have been associated with approximately a 3-fold increase in birth defects, in particular facial paralysis, limb defects, cerebral and cranial anomalies. If you have been exposed to Cytotec® during pregnancy, consult 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.

Women who may become pregnant during the period of treatment with the medicine must use a reliable contraceptive method, since Cytotec® may cause a miscarriage or damage to the uterus.The damage to the uterus is greater in the advanced stages of pregnancy, if you have had a caesarean section in the past or have given birth to five or more children. If you are trying to become pregnant, consult your doctor as you will have to stop treatment with Cytotec®. If you are a woman who has not yet gone through the menopause, your doctor will prescribe you Cytotec® only if you are at risk of developing ulcers due to using non-steroidal anti-inflammatory drugs (NSAIDs).

Driving and using machines
The medicine may cause dizziness; therefore, its use requires caution while driving a car and operating dangerous machines, until you know how the medicine affects you.

Important information about some of this medicine's ingredients
Cytotec® contains less than 1 mmol sodium (23 mg) per tablet, therefore it is considered as "sodium free".

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

Crushing/splitting/chewing is forbidden, since the effect of these modes of administration has not been examined.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take a dose as soon as you remember, unless it is time for the next dose. But never take a double dose!

Adhere to the treatment as recommended by the doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cytotec® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and seek medical assistance immediately if there are signs of an allergic reaction:
- swelling of the face, lips, tongue or throat (angioedema),
- difficulty in breathing,
- swelling of the extremities (hands and feet),
- there are signs of anaphylactic shock (severe hypersensitivity to the ingredients of the preparation, that may cause a drop in blood pressure up to loss of consciousness).

Contact a doctor immediately if:
- You get prolonged heavy or painful bleeding.
- You get abnormal contractions of the uterus.

The following side effects have been reported with Cytotec®:
Very common side effects (occur in more than 1 in 10 users):
Skin rash, diarrhea. Diarrhea is the most common side effect and is occasionally severe. The chance of developing diarrhea is reduced if Cytotec® is taken with food.

Common side effects (occur in up to 1 in 10 users):
Dyspepsia, nausea, vomiting, abdominal pain, bloating, constipation, dizziness, headache and birth defects (fetal malformations). If you become pregnant during treatment with the medicine, stop taking Cytotec® immediately and consult the doctor.

Uncommon side effects (occur in up to 1 in 100 users):
Irregular periods, period disorders, fever, severe uterine pain, vaginal bleeding in post-menopausal women.

Rare side effects (occur in up to 1 in 1,000 users):
Cramps; tearing of the uterine tissue (uterine rupture) after administration of prostaglandins in the second or third trimester of pregnancy, mainly in women with previous deliveries or women with a scar of a caesarean section. Seek urgent medical attention.

Additional side effects of unknown frequency (the frequency of these effects has not been established yet): allergic reactions (hypersensitivity), including swelling of the hands and feet, face, lips, tongue or throat and which may cause significant difficulty breathing; prolonged heavy or painful bleeding; chills; high body temperature, abnormal contractions of the uterus, bleeding from the uterus, residual placenta remaining in the uterus after birth, miscarriage or termination of pregnancy, amniotic fluid entering the mother's bloodstream causing an allergic reaction (amniotic fluid embolism), incomplete miscarriage and premature birth, fetal death.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 30˚C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Microcrystalline cellulose, hydroxypropyl methyl cellulose, sodium starch glycolate, milled hydrogenated castor oil flake.

What the medicine looks like and contents of the pack:
Cytotec® 200 mcg: hexagon-shaped, white-cream-colored tablet.

Registration holder and address:
Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Manufacturer's name and address: Piramal Healthcare UK Ltd., Northumberland, UK.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Cytotec® 200 mcg: 037.78.25161

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