

Misoprostol 200 microgram Tablets

What Misoprostol is and what it is used for

- Misoprostol 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. Misoprostol belongs to a group of medicines known as 'anti-ulcer agents'.
- The Misoprostol 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 Misoprostol tablets will replace these prostaglandins and help to protect your stomach and intestine, so you can continue getting benefit from your NSAID. Misoprostol also reduces acid and increases bicarbonate in your stomach secretions.
- Misoprostol can also be used to heal existing ulcers.

What you need to know before you take Misoprostol

Do not take Misoprostol:

- if you are allergic to misoprostol or any of the other ingredients of this medicine 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 Misoprostol. Tell your doctor if you have any of the following conditions to help him or her decide if Misoprostol 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 Misoprostol 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 Misoprostol.
- 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 Misoprostol if he is satisfied you are at high risk of developing ulcers from your NSAID medicine.

Other medicines and Misoprostol

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

You can take Misoprostol 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 Misoprostol with food, drink and alcohol.

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 Misoprostol if you are pregnant or plan to become pregnant. Your doctor will make you aware of the risks if you do become pregnant as Misoprostol 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 Misoprostol 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 Misoprostol if he is satisfied you are at high risk of developing ulcers from your NSAID medicine.

Misoprostol 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 Misoprostol and use a different treatment.

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

Do not breastfeed while taking Misoprostol.

Driving and using machines

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

How to take Misoprostol

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 Misoprostol with food. Misoprostol 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 Misoprostol tablets twice a day with food. Alternatively you can take one Misoprostol 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 Misoprostol 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 Misoprostol than you should

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

If you forget to take Misoprostol

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.

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 Misoprostol:

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 Misoprostol 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

Misoprostol immediately and seek medical advice.

Uncommon: may affect up to 1 in 100 people: fever, irregular periods, periods problems, severe uterine pain, some older women may have vaginal bleeding even though they have gone through themenopause

Rare: may affect up to 1 in 1,000 people: cramping, 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 abscar of a caesarean section. Seek urgent medical attention.

How to store Misoprostol

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