

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MISOPROSTOL PFIZER® (tablets)

Read this leaflet carefully before you start to take MISOPROSTOL PFIZER.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MISOPROSTOL PFIZER has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MISOPROSTOL PFIZER CONTAINS

The active ingredient of MISOPROSTOL PFIZER is misoprostol.

The inactive ingredients include; microcrystalline cellulose, sodium starch glycolate and hydrogenated castor oil.

2. WHAT IS MISOPROSTOL PFIZER USED FOR:

MISOPROSTOL PFIZER is used for co-administration with non-steroidal anti-inflammatory drugs (NSAIDs) for the prevention of gastric and duodenal ulcers, haemorrhagic lesions and erosions induced by NSAIDs.

3. BEFORE YOU TAKE MISOPROSTOL PFIZER:

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Do not take MISOPROSTOL PFIZER:

If you are pregnant or breast feeding.

If you are allergic to misoprostol or other prostaglandins or any of the other ingredients of MISOPROSTOL PFIZER.

Take special care with MISOPROSTOL PFIZER:

Some people will need special care from their doctors when they are taking MISOPROSTOL PFIZER. If the answer to any of the following questions is “yes”, you should talk to your doctor or pharmacist before taking MISOPROSTOL PFIZER as it may not be suitable for you:

- Have you ever had a reaction to misoprostol or any of its ingredients?
- Are you pregnant, trying to become pregnant, or breast-feeding?
- Do you suffer from diarrhoea?
- Do you suffer from dehydration?
- Do you suffer from inflammatory bowel disease?
- Do you suffer from low blood pressure?

Taking other medicines with MISOPROSTOL PFIZER:

MISOPROSTOL PFIZER sometimes affects the action of other medicines and sometimes MISOPROSTOL PFIZER is affected by other medicines. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed, including herbal medicines.

4. HOW TO USE MISOPROSTOL PFIZER:

Always take MISOPROSTOL PFIZER exactly as your doctor has instructed you. Your doctor will decide what dose is right for you. Check with your doctor or pharmacist if you are unsure.

MISOPROSTOL PFIZER is available as a tablet. Take the tablet as prescribed by your doctor.

If you take more MISOPROSTOL PFIZER tablets than you should:

If you have accidentally taken too many tablets, talk to your doctor straight away. You may require medical attention.

If you forget to take MISOPROSTOL PFIZER tablets:

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

5. POSSIBLE SIDE EFFECTS:

MISOPROSTOL PFIZER can have side-effects. Should your general health worsen while taking MISOPROSTOL PFIZER, please consult your doctor, pharmacist or other health care professional for advice.

Other side-effects include:

- Dizziness
- Headache
- Diarrhoea
- Abdominal pain
- Nausea
- Vomiting
- Vaginal bleeding
- Menstrual disorder

Tell your doctor if any other effects occur while you are on MISOPROSTOL PFIZER treatment.

6. STORING AND DISPOSING OF MISOPROSTOL PFIZER:

Store MISOPROSTOL PFIZER tablets out of reach and sight of children. This medicine is for you. Only a doctor can prescribe it for you. Do not share it with anyone else. It may harm them, even if they have the same symptoms as you. Do not use MISOPROSTOL PFIZER after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MISOPROSTOL PFIZER:

MISOPROSTOL PFIZER tablets are supplied in blister packs of 60 or 120 tablets packed in cartons

8. IDENTIFICATION OF MISOPROSTOL PFIZER:

MISOPROSTOL PFIZER tablets are white, scored, uncoated, flat, hexagonal-shaped tablets, debossed on one side "Searle" over "1461".

9. REGISTRATION NUMBER:

S/11.10/392

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd.

85 Bute Lane

Sandton 2196

South Africa

11. DATE OF PUBLICATION OF THIS PATIENT LEAFLET:

25 November 2011