

1.3.2 PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

ACEMISO

Misoprostol 200 mcg tablets

Read all of this leaflet carefully before you start taking **ACEMISO**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **ACEMISO** 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.

What is in this leaflet:

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

1. What ACEMISO is and what it is used for

ACEMISO 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. **ACEMISO** belongs to a group of medicines known as 'anti-ulcer medicines'.

The **ACEMISO** 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 **ACEMISO** tablets will replace these prostaglandins and help to protect your stomach and intestine, so you can continue getting benefit from your NSAID. **ACEMISO** also reduces acid and increases bicarbonate in your stomach secretions.

ACEMISO can also be used to heal existing ulcers.



2. What you need to know before you take **ACEMISO**

Do not take **ACEMISO**

- if you are allergic to misoprostol or any of the other ingredients of **ACEMISO** (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
- 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).
- If you have kidney disease or impaired renal function.

Warnings and precautions

Tell your doctor or health care provider before taking **ACEMISO**:

Special care should be taken with **ACEMISO**:

- if you are pregnant or plan to become pregnant. Due to the risk for the foetus, your treatment with **ACEMISO** 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 **ACEMISO**.
- 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 **ACEMISO** if he is satisfied you are at high risk of developing ulcers from your NSAID medicine.

Children:

Do not give **ACEMISO** to children under the age of 18 years because it is unlikely to be safe.

*Other medicines and **ACEMISO***

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)



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

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 **ACEMISO** if you are pregnant or plan to become pregnant. Your doctor will make you aware of the risks if you do become pregnant as **ACEMISO** may cause a miscarriage, premature birth or birth defects.

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

ACEMISO can cause a miscarriage or damage to your womb, so it is very important to use reliable contraception while taking this medicine. If you want to try for a baby, tell your doctor as you will have to stop taking **ACEMISO** and use a different treatment.

Do not breastfeed while taking **ACEMISO**.

Driving and using machines

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

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3. How to take ACEMISO

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 **ACEMISO** with food.

To heal ulcers in your stomach or duodenum



You should normally take two 200 microgram **ACEMISO** tablets twice a day with food. Alternatively you can take one **ACEMISO** 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 **ACEMISO** 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 ACEMISO than you should

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

If you forget to take ACEMISO

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

ACEMISO can have side effects.

Not all side effects reported for **ACEMISO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ACEMISO**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ACEMISO** and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to **ACEMISO**. You may need urgent medical attention or hospitalisation.

If you get any of the following symptoms, tell your doctor immediately or go to the casualty department at your nearest hospital:

- prolonged heavy or painful bleeding



- abnormal contractions of the womb

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

Frequent:

- skin rashes
- diarrhoea
- dizziness
- headache
- stomach pain
- constipation
- wind
- indigestion
- feeling or being sick
- Birth defects (foetal malformations).

Less frequent:

- fever
- irregular periods
- periods problems
- severe uterine pain
- some older women may have vaginal bleeding even though they have gone through the menopause
- cramping
- Tearing of the womb (uterine rupture)

Unknown frequency

- allergic reactions, including swelling of the hands and feet, face, lips, tongue or throat and which may cause great difficulty in breathing
- prolonged heavy or painful bleeding
- chills
- high temperature
- abnormal contractions of the womb
- bleeding from the womb
- placenta remaining in the womb after birth, termination or miscarriage
- amniotic fluid (the fluid which surrounds the baby when pregnant) entering the mother's bloodstream causing an allergic reaction
- incomplete miscarriage and premature birth
- foetal death



If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **ACEMISO**

5. How to store ACEMISO

Store all medicines out of reach of children.

Store at or below 25° C

Store in the original package in order to protect from moisture

6. Contents of the pack and other information

What **ACEMISO** contains

The active substance is misoprostol

The other ingredients are:

- microcrystalline cellulose
- sodium starch glycolate
- hydrogenated castor oil

What **ACEMISO** looks like and contents of the pack

White to off white, round, biconvex, uncoated tablets, plain on both sides

Tablets are packed in cold form ALU-ALU blister packs in cartons of 56, 60, 112 or 120 or 140 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

96 Hartley Road



Durban, 4091

This leaflet was last revised in

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