

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH056 trade name][†]
Misoprostol

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly .*

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours..
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [RH056 trade name] is and what it is used for
2. What you need to know before you take [RH056 trade name]
3. How to take [RH056 trade name]
4. Possible side effects
5. How to store [RH056 trade name]
6. Contents of the pack and other information

1. What [RH056 trade name] is and what it is used for

This medicine contains an active substance called misoprostol which is a version of a natural substance called prostaglandin E₁. It acts on the womb to produce contractions, and helps the cervix (the opening of the womb) to relax and widen so that a baby can pass through.

This medicine is used in the last stage of pregnancy (third trimester) to help normal labour begin, or to help remove the fetus if it has died in the womb or cannot survive normally (fetal anomaly). It may also be used, alone or with another medicine, mifepristone, to help remove the fetus completely if it dies at an earlier stage of pregnancy and is not expelled naturally.

The medicine may also be used to prevent or to stop bleeding immediately after childbirth (postpartum hemorrhage) if oxytocin (a commonly used injection) cannot be given.

If it is legal and permitted in your country, this medicine may be used for abortion (termination of pregnancy). It is usually used in combination with mifepristone or sometimes another medicine, letrozole,

2. What you need to know before you take [RH056 trade name]

Do not take [RH056 trade name]:

- if you are allergic to misoprostol or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other medicines that need to be combined with this one
- if you have had previous allergic reactions to other prostaglandin medicines.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

In addition, [RH056 trade name] must not be used for abortion if:

- you have inherited porphyria (a rare metabolic disorder)
- your adrenal gland does not work properly (adrenal failure)
- your pregnancy has not been confirmed by tests
- you have, or are suspected to have, a pregnancy growing outside the womb (ectopic pregnancy)

Warnings and precautions

Talk to your healthcare provider before taking [RH056 trade name], if

- you have had genital cutting or circumcision
- you have had a previous baby delivered by caesarean section, or have had surgery on your womb
- you have heart disease, or you are at risk of heart disease because of, for example, high blood pressure, high cholesterol, smoking or diabetes
- you have liver disease
- you are malnourished
- you have anaemia (low red blood cell count), or an illness that affects the clotting of your blood (makes you bleed easily)

If any of these apply, your health care provider will discuss with you whether [RH056 trade name] is suitable for you.

Before you receive [RH056 trade name] you will normally need to be checked by a health care provider to see how far along your pregnancy is. This might include an ultrasound scan.

If you have an intrauterine contraceptive device (coil), this must be removed before treatment.

Speak to your health care provider if you have any infection in your genital area, as this should be treated before you receive [RH056 trade name]. Also speak to your health care provider at once if you think you have an infection after you have been treated with [RH056 trade name].

Before taking [RH056 trade name] your blood may be tested for Rhesus factor. If you are Rhesus negative your health care provider will advise you of the routine treatment required.

Children and adolescents

Limited data are available for women under 18 years.

[RH056 trade name] should not be used in children below pubertal age.

Abortion

If you are being given [RH056 trade name] for an abortion, your health care provider should explain the procedure to you, including what medicines are needed and how to take them. They will also give you information about possible bleeding after the procedure, how to look after yourself and look out for complications that may occur, and how and where to get help.

Other medicines and [RH056 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Pregnancy

This medicine should not be used during pregnancy if you wish to go on and have the baby, unless it is used when the baby is ready to be born.

If you take [RH056 trade name] to terminate a pregnancy and the medicine does not work properly, your baby may be at risk of birth defects. It is not known how big the risk is.

If you still want to terminate your pregnancy another procedure will be used. Your health care provider will

talk to you about the options.

If you decide to continue with the pregnancy, careful pre-natal monitoring and repeated ultrasound scans must be carried out in a specialised clinic. Your health care provider will talk to you about this.

You should avoid getting pregnant again before your next period after taking this medicine. To avoid becoming pregnant, you should start contraception (birth control) immediately after your health care provider tells you that the termination of the pregnancy is successful.

Breast-feeding

You can breast-feed normally if you have received [RH056 trade name]. Only very low levels of misoprostol ever pass into breast milk and are not expected to affect your baby.

Fertility

[RH056 trade name] does not affect fertility. You can become pregnant again as soon as your pregnancy ends. You should start contraception immediately after the termination of the pregnancy is confirmed.

Driving and using machines

Headache, dizziness and tiredness can occur during treatment with misoprostol. If you get these effects you should avoid potentially hazardous tasks such as driving or operating machinery.

Important information about some of the ingredients of [RH056 trade name]

[RH056 trade name] contains hydrogenated castor oil. Patients may experience symptom such as stomach upset and diarrhea.

3. How to take [RH056 trade name]

The dose of [RH056 trade name] and the way in which it is used can vary depending on what it is being used for, and how far along your pregnancy is. ***Your health care provider will explain the right dose and how to take the medicine.***

Always use this medicine exactly as your healthcare provider has told you.

Check with your health care provider if you are not sure.

Starting labour (labour induction) or ending pregnancy if the fetus has died or cannot survive normally (fetal anomaly)

Your health care provider will dissolve a tablet of [RH056 trade name] in 200 mL of water and give you 25 mL of this mixture to swallow every 2 hours until labour starts.

Postpartum hemorrhage

To *prevent* bleeding after delivery of your baby (postpartum haemorrhage), the recommended dose is 2 or 3 tablets of [RH056 trade name] (400 or 600 micrograms of misoprostol) by mouth. Swallow the tablets whole and do not break or crush them.

If heavy bleeding does happen, and you cannot be given an injection of another medicine, oxytocin, to *treat* the bleeding, then you may be given 4 tablets of [RH056 trade name] to take by placing them under your tongue and leaving them there for half an hour (30 minutes) without swallowing. After 30 minutes, you should swallow anything that remains.

Induction of abortion (termination of pregnancy)

Medical termination of pregnancy at less than 12 weeks of gestation:

- if [RH056 trade name] is **used with the medicine mifepristone**: you will first take one tablet of mifepristone (200 mg) by mouth, then after *24 to 48 hours* you should take 4 tablets of [RH056 trade name] (800 micrograms of misoprostol). Your health care provider may ask you to take more doses of [RH056 trade name] to complete the procedure.

You can take the [RH056 trade name] in different ways. The tablets may be:

- inserted into your vagina, *or*
- placed under your tongue for 30 minutes, *or*
- held between your cheek and gums for 20 to 30 minutes.

Your health care provider will discuss with you how you can take the tablets.

- if [RH056 trade name] is **used alone**, the recommended dose is 4 tablets of [RH056 trade name] (800 micrograms of misoprostol). Your health care provider may ask you to take more doses of [RH056 trade name] to complete the procedure

You can take the [RH056 trade name] in different ways. The tablets may be:

- inserted into your vagina, *or*
- placed under your tongue for 30 minutes, *or*
- held between your cheek and gums for 20 to 30 minutes.

Your health care provider will discuss with you how you can take the tablets.

- If [RH056 trade name] is **used with the medicine letrozole**, you will first need to take 1 tablet of letrozole (10 mg) by mouth each day for 3 days then on the fourth day you should take 4 tablets of [RH056 trade name] (800 micrograms of misoprostol).

You should place the [RH056 trade name] tablets under your tongue and leave them there for half an hour (30 minutes) without swallowing. After 30 minutes, you should swallow anything that remains.

Medical termination of pregnancy at 12 weeks of gestation or more

- if [RH056 trade name] is **used with the medicine mifepristone**: you will first take one tablet of mifepristone (200 mg) by mouth, then after *24 to 48 hours* you should take 2 tablets of [RH056 trade name] (400 micrograms of misoprostol) every 3 hours until the procedure is complete.

You can take the [RH056 trade name] in different ways. The tablets may be

- inserted into your vagina, *or*
- placed under your tongue for 30 minutes, *or*
- held between your cheek and gums for 20 to 30 minutes.

Your health care provider will discuss with you how you can take the tablets.

- if mifepristone cannot be used and [RH056 trade name] is to be **used alone**, the recommended dose is 2 tablets of [RH056 trade name] (400 micrograms of misoprostol) every 3 hours until the procedure is complete.

Before surgical termination of pregnancy at less than 12 weeks of gestation

- If you have a surgical termination in early pregnancy, [RH056 trade name] may be given before the procedure to relax and widen the opening of the womb and so make the procedure easier. The recommended dose is 2 tablets of [RH056 trade name] (400 micrograms of misoprostol).

The medicine can either be given:

- 1 to 2 hours before the procedure by placing the tablets under the tongue for 30 minutes, *or*
- 2 to 3 hours before the procedure by inserting the tablets in the vagina, *or*
- 2 to 3 hours before the procedure by holding the tablets between your cheeks and gums for 20 to 30 minutes.

Your health care provider will discuss with you how you should take the tablets.

Treatment for incomplete abortion

If you have had a partial miscarriage, or a termination procedure that has not worked properly (incomplete abortion), [RH056 trade name] may be given to help complete the process and expel the contents of the womb. The usual recommended dose depends on how far along your pregnancy was.

Less than 14 weeks of gestational age:

Either swallow 3 tablets of [RH056 trade name] (600 micrograms of misoprostol), **or** place under your tongue 2 tablets of [RH056 trade name] (400 micrograms of misoprostol) 30 minutes and then swallow the remainder.

More than 14 weeks of gestational age:

Place under your tongue 2 tablets of [RH056 trade name] (400 micrograms of misoprostol) for 30 minutes, **or** insert 2 tablets into the vagina, **or** hold 2 tablets between your cheeks and gums for 20 to 30 minutes.

Your health care provider will discuss with you the best way to take the tablets.

Missed abortion at less than 14 weeks of gestational age

If your pregnancy has stopped developing early on, and is not expelled naturally from the womb (missed abortion), then you may be given

- a dose of mifepristone (200 mg) by mouth, *followed after at least 24 hours by*
- 4 tablets of [RH056 trade name] (800 micrograms of misoprostol). You can insert the [RH056 trade name] tablets into your vagina, *or* place them under your tongue for 30 minutes, *or* hold them between your cheek and gums for 20 to 30 minutes. Your health care provider will discuss with you how you should take the tablets.

Death of the baby in the womb (intrauterine fetal death) at 14 to 28 weeks of gestational age

If your baby dies in the womb, and is not expelled naturally from the womb (stillbirth), then you may be given

- a dose of mifepristone (200 mg) by mouth, *followed after at least 24 hours by*
- 4 tablets of [RH056 trade name] (800 micrograms of misoprostol). You may insert the [RH056 trade name] tablets into your vagina, *or* place them under your tongue for 30 minutes, *or* hold them between your cheek and gums for 20 to 30 minutes. Your health care provider will discuss with you how you should take the tablets.

Taking [RH056 trade name] with food

If you are swallowing the tablets whole, it is better to take your dose on an empty stomach (at least half an hour before or two hours after eating) if possible. However, in an emergency you can swallow [RH056 trade name] tablets even if you have eaten recently.

If you take more [RH056 trade name] than you should

If you have taken too much misoprostol you may get effects such as: fever, changes in blood pressure or effects on the heart, feeling sick (nausea), diarrhoea, belly ache (abdominal pain) and shaking (tremors).

If you have accidentally taken too many tablets, contact your healthcare provider as soon as you can.

If you forget to take [RH056 trade name]

If you forget to take [RH056 trade name] the procedure may not work properly. Talk to your health care provider if you forget to take [RH056 trade name].

If you have any further questions on the use of this medicine, ask your healthcare provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may vary somewhat depending on the way in which the medicine is given and the condition it is being used for.

The side effects that may be seen when [RH056 trade name] is given for prevention of postpartum haemorrhage are:

Very common side effects (*may affect more than 1 in 10 people*)

- feeling sick (nausea),
- shivering
- fever (including temperature above 40°C).

Common side effects (*may affect up to 1 in 10 people*)

- headache
- dizziness/fainting
- being sick (vomiting)
- diarrhoea
- chills

Uncommon side effects (*may affect up to 1 in 100 people*)

- tiredness
- rash.

Rare side effect (*may affect up to 1 in 1,000 people*)

- nettle rash (hives), reddening of the skin, severe skin rashes.

Very rare side effect (*may affect fewer than 1 in 10 000 people*)

- angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs)

Other side effects that have occurred include heart problems, severe allergy, back pain, and fetal malformation.

When used for induction of labour, cramping and injury (rupture) of the womb have also been reported as well as distress to the unborn.

When used for abortion, cramping of the womb, prolonged menstrual-like bleeding (on average for 9 days and up to 45 days) and incomplete expulsion of the contents of the womb have been reported. Rarely genital infection and injury (rupture) of the womb may occur.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [RH056 trade name]

Keep this medicine out of the sight and reach of children.

Keep this medicine out of the sight and reach of children.

Store below 30°C. Store tablets in blisters in the provided cartons.

Do not use this medicine after the expiry date stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [RH056 trade name] contains

- The active ingredient is misoprostol.
- The other ingredients of [RH056 trade name] are hydrogenated castor oil, hypromellose, microcrystalline cellulose and sodium starch glycolate.

What [RH056 trade name] looks like and contents of the pack

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

The tablets are packed in cold form aluminium (Alu-Alu) blister packs of 10 tablets. Each carton contains 10 such blisters packs. Pack size: 10x10 Tablets

The tablets were packed in cold form aluminium (Alu-Alu) blister of 3 tablets one such blister packed in monocarton and Each outer carton contains 10 such monocarton of 1 blister each. Pack size: 10x1x3 Tablets

The tablets were packed in cold form aluminium (Alu-Alu) blister of 4 tablets one such blister packed in monocarton and Each outer carton contains 10 such monocarton of 1 blister each. Pack size: 10x1x4 Tablets

The tablets were packed in cold form aluminium (Alu-Alu) blister of 4 tablets one such blister packed in monocarton and Each outer carton contains 15 such monocarton of 1 blister each. Pack size: 15x1x4 Tablets

The tablets were packed in cold form aluminium blister of 10 tablets. Each carton contains 6 such blister. Pack size: 6x10 Tablets

The tablets should not be divided.

Supplier and Manufacturer

Supplier

ACME Formulation Pvt. Ltd.
Ropar Road, Nalagarh, Dist. Solan Himachal
Pardesh-174101
India
Tel.: +91-1795-228507
Fax: +91-1795-228600
E-mail: viralshah@acmeformulation.com

Manufacturer

ACME Formulation Pvt. Limited (Hormone
Block) Ropar Road, Nalagarh Dist. Solan
Himachal Pradesh-174101
India
Tel.: +91-1795-228507
Fax: +91-1795-228600
E-mail: viralshah@acmeformulation.com

For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>