Medical abortion

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- MISO-FEM® Product Information

ABORTION

Overview

Abortion overview – Key facts

1

73.3M

Abortions occurred each year between 2015 & 2019[1]

2

61%

of unintended pregnancies ended in an induced abortion[1]

3

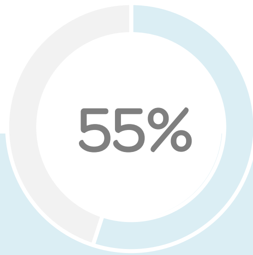
80.000

maternal deaths per year due to abortion[2]

[1]Bearak J, Popinchalk A, Ganatra B, Moller A-B, Tunçalp Ö, Beavin C, Kwok L, Alkema L. Unintended pregnancy and abortion by income, region, and the legal status of abortion: estimates from a comprehensive model for 1990–2019. Lancet Glob Health. 2020 Sep; 8(9):e1152-e1161. doi: 10.1016/S2214-109X(20)30315-6.

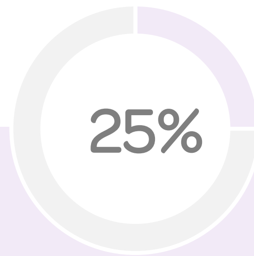
[2]Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, Gülmezoglu AM, Temmerman M, Alkema L. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014 Jun; 2(6):e323-33.

Abortion overview – Key facts



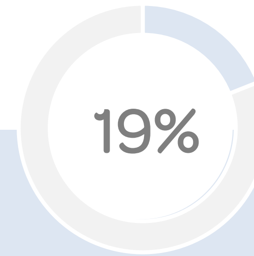
Safe Abortions

Safe abortion is an abortion provide by a trained person with a WHO qualified method (Medical abortion, Vaccum aspiration, Dilatation and evacuation)



Less Safe Abortions

An abortion is less safe when only one of the two criteria is met

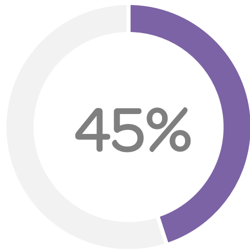


Unsafe Abortions

An abortion is classified least safe if it provided by untrained individual using unqualified method

https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion
Internal Source

Abortion overview – Key facts



Approximately 45% of all abortions worldwide were unsafe or less safe.

Number of abortion per country

Number of abortions

12985 859

2 006

Avec Bing

© GeoNames, Microsoft, Navinfo, OpenStreetMap, TomTom, Wikipedia

Over half of all estimated unsafe abortions globally were in Asia, most of them in south and central Asia

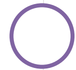
The risk of dying from an unsafe abortion was the highest in Africa

3 out of 4 abortions that occurred in Africa and Latin America were unsafe

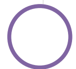
https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion
Internal Source

Complications of unsafe abortion

Unsafe abortions when performed under least safe conditions can lead to complications such as:

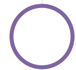


incomplete abortion (failure to remove or expel all the pregnancy tissue from the uterus)



hemorrhage (heavy bleeding)

infection



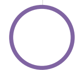
uterine perforation (caused when the uterus is pierced by a sharp object)

damage to the genital tract and internal organs by inserting dangerous objects such as sticks, knitting needles, or broken glass into the vagina or anus.

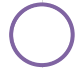
https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion

Barriers to safe abortion

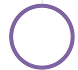
Barriers to accessing safe abortion include:



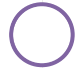
restrictive laws



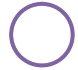
poor availability of services



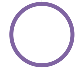
high cost



stigma



conscientious objection of health-care providers and

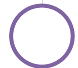


unnecessary requirements, such as mandatory waiting periods, mandatory counselling, provision of misleading information, third-party authorization, and medically unnecessary tests that delay care.

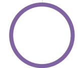
https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion

Prevention

Unsafe abortion can be prevented through:

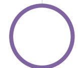


comprehensive sexuality education;

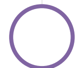


prevention of unintended pregnancy through use of effective contraception, including emergency contraception;

education for women and HCP's;



availability of services; and



provision of safe, legal abortion.

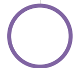
https://www.who.int/news-room/fact-sheets/detail/preventing-unsafe-abortion

ABORTION METHODS

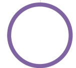
Overview

Abortion methods overview

Recommended methods of abortion by pregnancy duration:



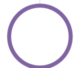
medical abortion (MA)



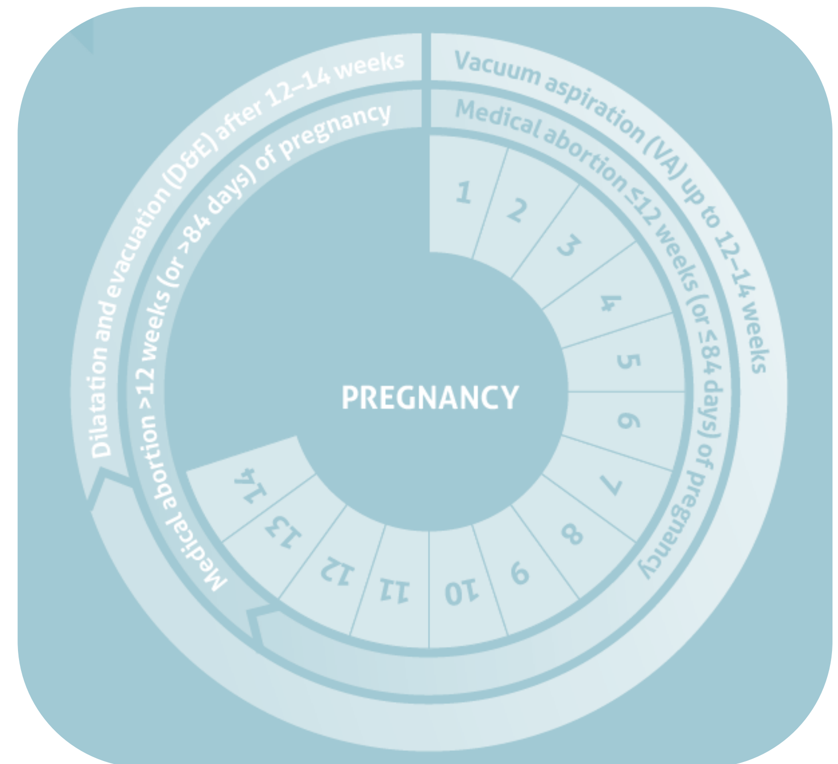
Vacuum aspiration

Manual vacuum aspiration (MVA)

Electric vacuum aspiration (EVA)

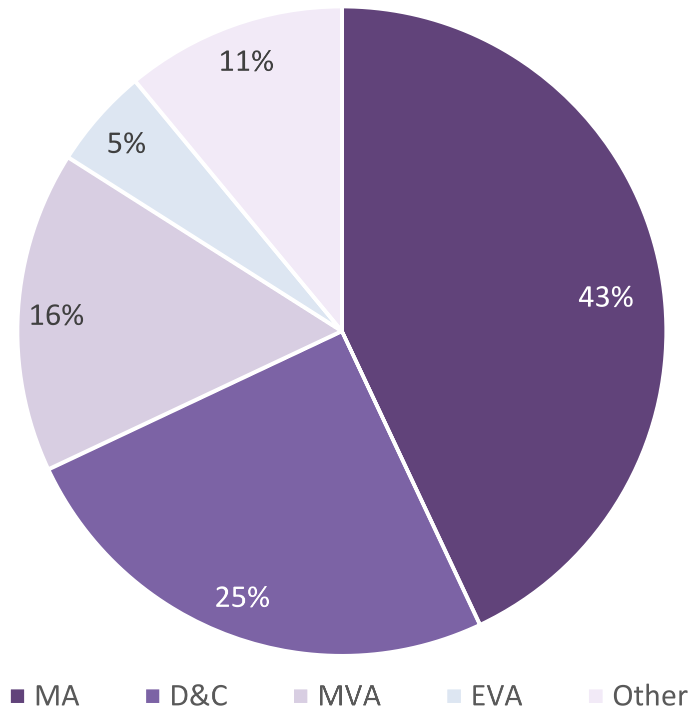


Dilation and evacuation (D&E) - 2nd trimester procedures



Clinical practice handbook for Safe abortion, World Health Organization, 2014

Abortion methods overview



MA

MA is the **preferred method worldwide**, specially in Northern Europe (97%**), followed by Southern Asia (72%), Northern America (59%) and Western Europe (56%).

D&C

D&C is declining as abortion method in many countries. Hospitals in less developed countries and rural areas stick to this abortion method. This practice is prevalent in Central America, Western and Central Asia, Middle Africa. This method can be used regardless of the gestational age.

MVA

MVA is the third most popular abortion method worldwide. It is widely spread in South America, Southern and Eastern Africa and Southern Europe. MVA is losing ground in North America and Europe (esp. Northern and Western Europe),being gradually replaced by medical abortion.

Internal Souce: Global MVA Abortion Market MarketSize, Trends and Competitive Landscape, 2021

Abortion methods overview

- MVA is recommended for uterine evacuation at <14 weeks as an alternative to electronic suction and dilatation and curettage
- Manual vacuum aspiration should replace the D&C as a uterine evacuation method
- Sharp curettage performed alone or in combination with vacuum aspiration is significantly more likely to be associated with complications including incomplete abortion than vacuum aspiration used alone
- D&C should be considered obsolete.

World Health Organization. (2022). Abortion care guideline. World Health Organization. https://apps.who.int/iris/handle/10665/349316. License: CC BY-NC-SA 3.0 IGO
4. FIGO. (2011). Consensus statement on uterine evacuation. Retrieved from https://www.figo.org/news/figo-consensus-statement-uterine-evacuation
Sekiguchi, A., Ikeda, T., Okamura, K., & Nakai, A. (2015). Safety of induced abortions at less than 12 weeks of pregnancy in Japan. International Journal of Gynecology & Obstetrics, 129(1), 54-57.

Abortion methods overview

Region	Subregion	Surgical abortion method			Medical	Other	
		% MVA	%EVA	%D&C	%MA	Other methods	Based on country data:
Africa	Eastern Africa	34	4	14	36	12	Kenya, Tanzania, Rwanda, Ethiopia
	Middle Africa	8	1	43	48	0	Uganda
	Northern Africa	na	na	na	na	na	Egypt
	Southern Africa	63	7	limited	30	0	South Africa
	Western Africa	17	20	0	6	57	Nigeria, Ivory Coast
Asia	Central Asia	20	14	45	21	0	Pakistan
	Eastern Asia	7	3	41	26	23	Japan, China
	Southeastern Asia	na	na	na	na	na	Thailand
	Southern Asia	6	2	20	72	0	India, Bangladesh
	Western Asia	35	10	45	10	0	Turkey
America	Caribbean	na	na	na	na	na	
	Central America	14	0	45	20	21	Guatemala, Costa Rica
	South America	33	13	10	32	12	Brazil
	Northern America	23	17	1	59	0	USA, Mexico
Europe	Eastern Europe	na	na	na	na	0	Ukraine, Romania
	Northern Europe	1	2	0	97	0	Sweden, Finland
	Southern Europe	35	38	0	27	0	Italy, Spain
	Western Europe	22	12	10	56	0	Germany, France, UK
	Oceania	67 (all surgical)			11	20 (vacuum and MA)	Australia

Internal Souce: Global MVA Abortion Market MarketSize, Trends and Competitive Landscape, 2021

Comparison of Abortion methods <14w

Importance of counselling and patient choice

Medical abortion before 14 weeks with **Mifepristone and Misoprostol, or Misoprostol only**	MVA before 14 weeks
Avoid surgery	Quick procedure, takes around 15 minutes
Mimics the process of miscarriage	Complete abortion easily verified by evaluation of aspirated product of conception
In some settings and gestations it can take place at home	Takes place in a health facility
Takes hours or days to complete the abortion which can be unpredictable. Women will experience bleeding and cramping during this time	Intrauterine contraception can be provided at the end of the procedure
Tablets may cause other side effects such as vomiting, shivering and nausea	Requires instrumentation of the uterus
May require more than one visit to the clinic if bleeding and pain require treatment and to ensure that the pregnancy has passed	Small risk of uterine or cervical injury
There is a chance that women may see the products of conception.	Timing if the abortion is controlled by the provider and the clinic
On average for every 1000 women only one will have a serious complication*	On average for every 1000 women only one will have a serious complication
On average for every 1000 women about 70 will need to have uterine evacuation to complete the abortion	On average for every 1000 women about 35 will need to have an additional uterine evacuation to complete the abortion

Medical abortion (MA)

Overview

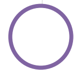
Medical abortion (MA)

- Mifepristone and Misoprostol or Misoprostol alone
- For management of induced abortion, miscarriage, incomplete abortion
- Mifepristone with Misoprostol is more effective than Misoprostol used alone for induced abortion
- MA is safe, effective and suitable for almost all women
- May take place at home so it improves privacy, convenience and acceptability, without compromising on safety, when available
- Women must be able to access counselling and emergency care in the event of complications or if they have questions
- Mifepristone and Misoprostol do not terminate pregnancies

Goodman S, Flaxman G, and the TEACH Trainers Collaborative Working Group.* TEACH Early Abortion Training Workbook, Fifth Edition. UCSF Bixby Center for Global Reproductive Health: San Francisco, CA (2016).

Medical Management of Induced Abortion <12 w*

KEY HUMAN RIGHTS CONSIDERATIONS RELEVANT TO MEDICAL ABORTION



Everyone has a right to privacy and confidentiality in sexual and reproductive health (SRH) care.

- Abortion regulation should be human rights and evidence based.
- States must ensure adequate access to essential medicines in an affordable and nondiscriminatory manner.
- Everyone has the right to scientific progress and right to health, which requires the availability and accessibility, acceptability, and quality of medical abortion. This means that States should ensure access to abortion medicines, and that evidence-based standards and guidelines for the provision and delivery of SRH services, are
  - (i) in place and
  - (ii) routinely updated to incorporate medical advancements.

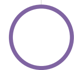
*Abortion care guideline. Geneva: World Health Organization; 2022.

Medical abortion (MA)

Mechanism of action

Mifepristone

- Stops the pregnancy from growing by blocking the hormone progesterone
- This normally sustains the pregnancy
- Used combined with misoprostol in a *set dosing sequence*



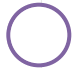
Misoprostol

- Stimulates the uterus to contract and empty by softening the cervix
- Can be used without mifepristone where this is not available
- Initially used for protecting the stomach lining

Note: Letrozole is a less common drug but acts in a similar way to Mifepristone.

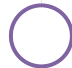
Medical abortion (MA)

Contraindications



Mifepristone

- Adrenal suppression (may require corticosteroid);
- Anticoagulant therapy;
- Asthma (avoid if severe and uncontrolled);
- Existing cardiovascular disease;
- Haemorrhagic disorders;
- History of endocarditis;
- Prosthetic heart valve;
- Risk factors for cardiovascular disease



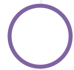
Misoprostol

- Cardiovascular disease;
- Risk factors for cardiovascular disease

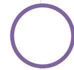
Allergies to the medication

Medical abortion (MA)

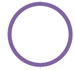
Estimation of gestational age



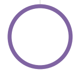
This is essential to ensure that the gestation is accurate so that the woman receives the correct doses of medication.



Medical abortion at later gestations should be performed in a healthcare facility because of increased risk of bleeding.



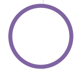
Gestational age can be reasonably estimated in most cases as the number of weeks and days from the first day of the last normal menstrual period (LMP).



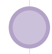
Perform ultrasound or physical exam if there are doubts about gestation, or suspicion of ectopic pregnancy

Medical abortion (MA)

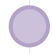
Medical Management of Induced Abortion <12 w*



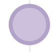
Combination of Mifepristone and Misoprostol



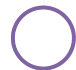
200 mg Mifepristone administered orally, followed 1–2 days later by 800 ag Misoprostol



Administered vaginally, sublingually or buccally

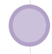


The minimum recommended interval between use of Mifepristone and Misoprostol is 24 hours.*

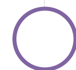


Misoprostol only

800 ag misoprostol administered buccally, sublingually, vaginally



Repeat doses of Misoprostol can be considered when needed to achieve success of the abortion



Combination Letrozole plus Misoprostol

Letrozole 10 mg orally each day for 3 days followed by misoprostol 800 ag sublingually on the fourth day) as a safe and effective option

*Abortion care guideline. Geneva: World Health Organization; 2022.

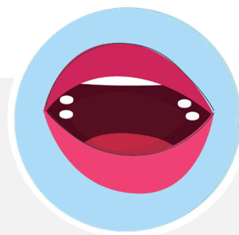
Medical Management of Induced Abortion

Oral

pills are swallowed immediately

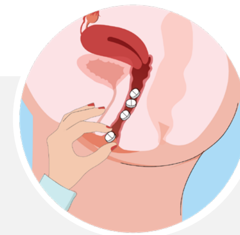
Sublingual

pills are placed under the tongue and swallowed after 30 minutes



Buccal

pills are placed between the cheek and gums and swallowed after 20 to 30 minutes



Vaginal

pills are placed in the vagina right up next to the cervix

Medical abortion (MA)

Medical Management of Induced Abortion <12 w*

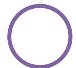
Pre abortion ultrasound is not essential

Local regulation may demand it, but may reduce access

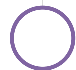
Pain management

Should be offered routinely (e.g. non-steroidal anti-inflammatory drugs [NSAIDs])

It should be provided for the individual to use if and when wanted.



Use of anti D to prevent rhesus isoimmunisation is not indicated <12w



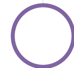
Prophylactic antibiotics are not indicated for medical abortion

Medical abortion (MA)

Side Effects

Cramping/pain
occurs in >90% of patients, varies in intensity, peaks after misoprostol dose.

Nausea, vomiting, diarrhea, low-grade fever, chills and myalgias
are common side effects of misoprostol, and usually resolve within 6 hours of use.



Vaginal bleeding
is usually heaviest within 4-6 hours after misoprostol, often heavier than normal menses and accompanied by the passage of clots.

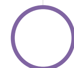
Medical abortion (MA)

Importance of an open door policy
"Come back any time"

Follow up care

Women must be adequately informed about:

- symptoms of ongoing pregnancy (which may or may not indicate failure of the abortion)
- prolonged heavy bleeding or no bleeding at all with medical management of abortion,
- pain not relieved by medication
- fever

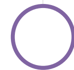


There is no medical need for a mandatory routine follow-up unless the woman wishes to be assessed

Medical abortion (MA)

Telemedicine

Option as alternative to in-person interactions with the health worker to deliver medical abortion services in whole or in part.



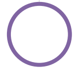
Telemedicine services should include Referrals

- (based on the woman's location) for medicines (abortion and pain control medicines)
- for any abortion care or post-abortion follow-up required (including for emergency care if needed
- post-abortion contraceptive services,

Medical abortion (MA)

Self management MA <12w

Importance of counselling and accessible high quality information

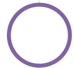


For medical abortion at < 12 weeks (using the combination of mifepristone plus misoprostol or using misoprostol option of self-management of the medical abortion process in whole or any of the three

- self-assessment of eligibility (determining pregnancy duration; ruling out contraindications)
- self-administration of abortion medicines outside of a health-care facility and without the direct supervision of a trained health worker, and management of the abortion process
- self-assessment of the success of the abortion

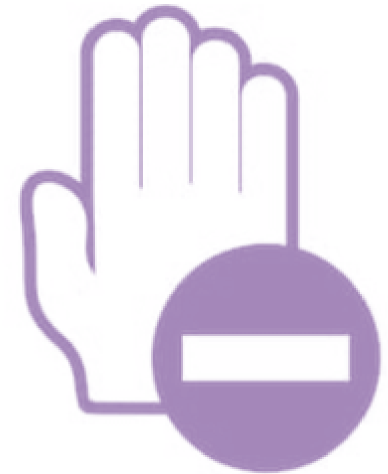
Medical abortion (MA)

Complications



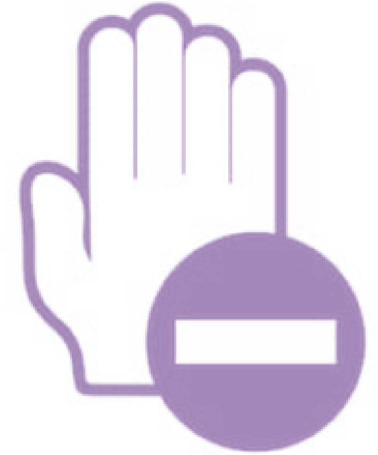
The patient should reach the HCP or emergency services if:

- There is no bleeding within 24 hours of Misoprostol
- Soak 2 or more maxi-pads for 2 or more consecutive hours
- Unmanageable pain despite taking analgesics prescribed
- Sustained fever >38°C or 100.4°F or onset of fever >24 hours after Misoprostol
- Abdominal pain, weakness, nausea, vomiting or diarrhea more than 24 hours after Misoprostol



Goodman S, Flaxman G, and the TEACH Trainers Collaborative Working Group.* TEACH Early Abortion Training Workbook, Fifth Edition. UCSF Bixby Center for Global Reproductive Health: San Francisco, CA (2016).

Medical abortion (MA)

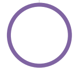


- If there is no bleeding after taking pills consider
  - Confirming the existence of a pregnancy
  - Is there a continuing pregnancy, risk 1-2 per 100: if confirmed, a hcp should discuss repeat medication or MVA
  - Ectopic pregnancy: may be asymptomatic or present with minimal bleeding
- Heavy or prolonged bleeding after expulsion of the pregnancy (uterine aspiration may be required)
  - Severe bleeding requiring transfusion less than 1 per 1000
- Overall, need for additional procedure to complete the process is required in 70 per 1000 cases
- Infection is rare (less than 1per 100)
- Once misoprostol taken, abortion must be completed due to potential misoprostol teratogenicity (associated with increased congenital deformities).

Best Practice in Abortion Care, Royal College of Obstetricians and Gynaecologists, April 2022

Medical abortion (MA)

Has the medical abortion procedure been successful?



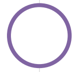
Consider the following signs that may indicate the treatment has **not** been successful

- No bleeding or only slight spotting within 24 hours of taking misoprostol tablets.
- Less than 4 days of bleeding.
- Continued pregnancy symptoms or feeling pregnant, such as sore breasts, nausea, or a growing abdomen, by the end of the first week.
- A positive, invalid, or unclear result on the urine pregnancy test taken 3 weeks after treatment (using the first morning urine).
- No onset of the next period by 4 weeks after treatment, even if the pregnancy test was negative.

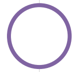
* British Pregnancy Advisory Service (BPAS). Abortion aftercare. https://www.bpas.org/abortion-care/abortion-aftercare/.

Medical abortion (MA)

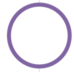
Summary



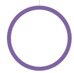
Mifepristone + Misoprostol, or Misoprostol alone are safe and effective treatments for uterine evacuation for induced abortion and early pregnancy loss



medical abortion does not require a surgical procedure and does not need to be arranged around the availability of a provider

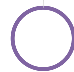


Medication can be self administered successfully with good quality counselling



MVA should be accessible for all women who choose medical abortion in cases where the woman changes her mind or uterine evacuation is incomplete

Source Material



Abortion care guideline. Geneva: World Health Organization; 2022. Abortion care guideline (who.int)

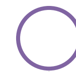
MISOMIFE-FEM® COMBO

ABORTION PILL

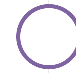
Product Information

Misomife-Fem® Combo

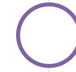
Product Overview



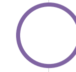
Formulation:
1 tablet of Mifepristone 200 mg
4 tablets of Misoprostol 200 mcg



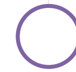
Classification:
Abortion pills



Available presentation:
1 tablet of Mifepristone
4 tablets of Misoprostol



Used for:
medical abortion up to 12 weeks of gestation.

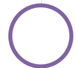


Storage conditions:
Below 30°C away from direct sunlight and keep out from the reach of children. Not to be taken by children.

¨Patient Information Leaflet

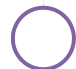
Misomife-Fem® Combo

Mechanism of action



Mifepristone

- Stops the pregnancy from growing by blocking the hormone progesterone
- This normally sustains the pregnancy
- Used combined with misoprostol



Misoprostol

- Stimulates the uterus to contract and empty by softening the cervix

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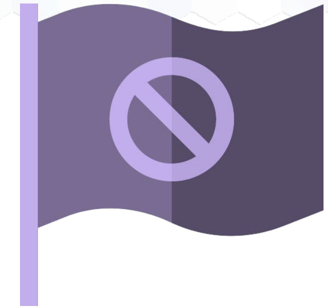
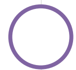
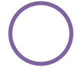
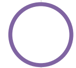
Misomife-Fem® Combo

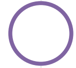


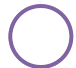
Contraindications

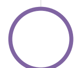

Confirmed or presumed ectopic pregnancy or undiagnosed adnexal mass.

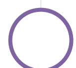

Pregnancy of more than 63 days of amenorrhea.

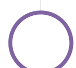

IUD placed

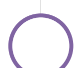

Chronic adrenal insufficiency


Concurrent long-term corticosteroid therapy


In case of allergy to Mifepristone, Misoprostol or other prostaglandin.


Bleeding disorders or concurrent treatment with anticoagulants.

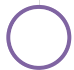

Hereditary porphyrias.


Inadequate access to medical facilities equipped to provide incomplete emergency abortion treatment.

¨Patient Information Leaflet

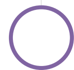
Misomife-Fem® Combo

Side Effects



The following side effects may occur after taking the MISOMIFE-FEM® COMBO:

- Vaginal bleeding and uterine cramps are normal as they are needed to produce an abortion.
- Nausea
- Vomiting
- Diarrhea

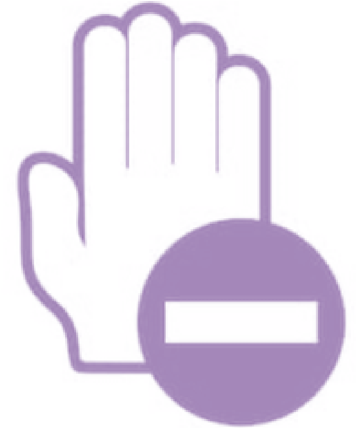


Some adverse reactions reported within 4 hours after administration of Misoprostol have been reported to be more severe than others:

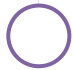
- Pain due to uterine contractions
- Heavy vaginal bleeding
- Pelvic pain
- Gastrointestinal side effects such as diarrhea, abdominal pain, nausea, flatulence, dyspepsia, headache, vomiting and constipation.

¨Patient Information Leaflet

Misomife-Fem® Combo



Precautions

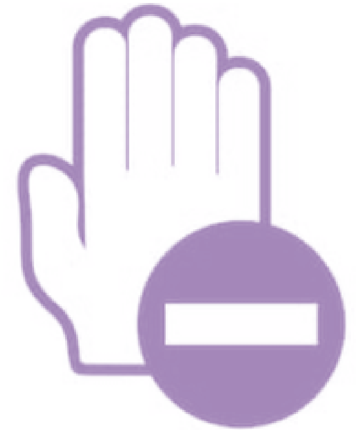


Mifepristone

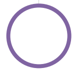
- Prolonged severe bleeding may be a sign of incomplete abortion or other complications, and immediate medical or surgical intervention may be needed to prevent the development of hypovolemic shock.
- Infection and septicemia: a high level of suspicion is needed to rule out septicemia if a patient reports abdominal discomfort or pain or general discomfort (including vomiting, weakness, nausea, or diarrhea) for more than 24 hours after taking Misoprostol.
- Ectopic pregnancy: Mifepristone is contraindicated for patients with confirmed or suspected ectopic pregnancy.

¨Patient Information Leaflet

Misomife-Fem® Combo



Precautions

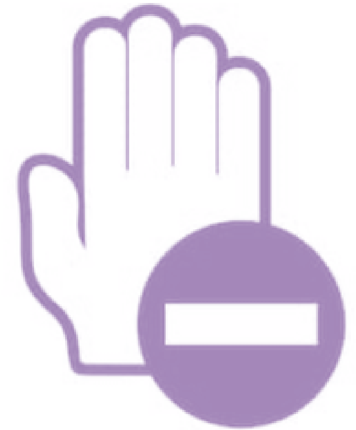


Misoprostol

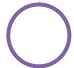
- The patient may experience gastrointestinal cramps and disorders after taking Misoprostol.
- The patient should also be informed of the measures to be taken in case of major discomfort, excessive bleeding or other adverse reactions.
- The intrauterine device (IUD) should be withdrawn before starting the treatment with Misoprostol.
- Treatment may cause malformation of the fetus in patients who have a current pregnancy.
- Oxytocin should not be used after 6 hours of administration of the last dose of Misoprostol. It may increase the risk of uterine tachysole, uterine hernia, meconium passage, meconium staining of the amniotic fluid and cesarean delivery due to uterine hyperstimulation with the use of high doses of Misoprostol.

*Patient Information Leaflet

Misomife-Fem® Combo

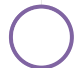


Drug Interactions



Mifepristone

- It is possible that ketoconazole, itraconazole, erythromycin and grapefruit juice may inhibit the metabolism of hepatic enzymes such as CYP3A4.
- CYP3A4 inducers such as rifampin, St John's wort and certain anticonvulsants (phenytoin, phenobarbital, carbamazepine) mainly used as anticonvulsants or anti-epileptics, but there also some of these drugs that are used for other purposes.



Misoprostol

- Its side effects (diarrhea and abdominal pain) may increase with the interaction with antacids.

¨Patient Information Leaflet

MISO-FEM®

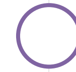
Product Information

Miso-Fem®

Product Overview

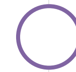
Formulation:

Misoprostol 200 mcg each tablet



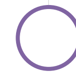
Available presentation:

4 tablets of Mifoprostol
12 tablets of Misoprostol



Used for:

Treatment of induced abortion
Treatment miscarriage and incomplete abortion
Treatment of postpartum hemorrhage
Prevention of postpartum hemorrhage



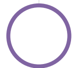
Storage conditions:

Below 30°C away from direct sunlight and keep out from the reach of children. Not to be taken by children.

¨Patient Information Leaflet

Miso-Fem®

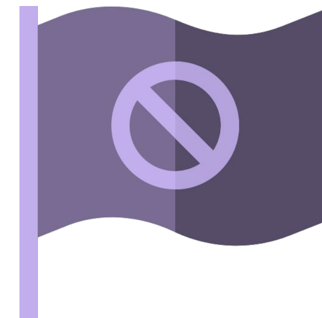
Mechanism of action

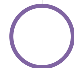


Misoprostol

- Stimulates the uterus to contract and empty
- Prostaglandin analog used for first trimester abortions. The stimulation of prostaglandin in the uterus and cervix can increase the strength and frequency of contractions and decrease cervical tone.

Contraindications



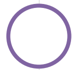


In case of allergy to Prostaglandin

¨Patient Information Leaflet

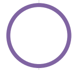
Miso-Fem®

Other reproductive health uses



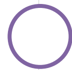
Treatment of postpartum haemorrhage (PPH)

- Rectal administration of 1,000 mcg significantly reduces the need for additional interventions, especially in women who have not received misoprostol for prevention of PPH.
- The sublingual dose of 800 mcg of misoprostol may also be administered.

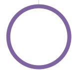


Prevention of postpartum haemorrhage (PPH)

- 600 mcg by oral administration immediately after delivery and after confirmation that all fetuses have been born



Induction of labour at term (25 mcg dose)

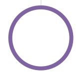


Management of intrauterine fetal demise (IUFD) ≥ 14 to ≤ 28 weeks:

- 200 mg mifepristone administered orally, followed 1–2 days later by repeat doses of 400 αg misoprostol administered sublingually or vaginally every 4–6 hours or
- repeat doses of 400 αg misoprostol administered sublingually or vaginally every 4–6 hours.

Misomife-Fem® Combo

Side Effects

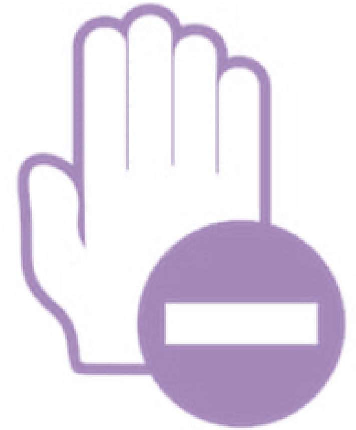


The following side effects may occur after taking the MISO-FEM® :

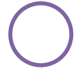
- Mild chills and fever (usually no more than 38-39 °C)
- Nausea
- Flatulence
- Dyspepsia
- Vomiting
- Constipation

¨Patient Information Leaflet

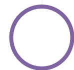
Miso-Fem®



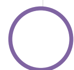
Precautions



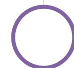
Twin or multiple pregnancies (twins, triplets, etc.): all fetuses must be born before administering Miso-fem®, as the uterine contractions caused by Misoprostol can endanger the lives of fetuses still found in the uterus.



Teratogenic effects: Congenital anomalies are sometimes associated with fetal death due to failure of subsequent use as an abortifacient. This effect is the likely outcome of a temporary vascular alteration in the placental fetal unit due to contractions and bleeding caused by Misoprostol. The use of Misoprostol during the first trimester of pregnancy has been associated with defects in the skull, cranial nerve palsies, poor facial formation and limb defects.



Non-teratogenic effects: Miso-fem® may endanger the pregnancy (causing contractions and may cause bleeding) and therefore may harm the fetus when administered to a pregnant woman. Miso-fem® produces contractions in the uterus and expulsion of the products of conception.



Breastfeeding: Misoprostol enters breast milk. However, after 5 hours of taking a single oral dose of 600 mcg of Misoprostol, the content of Misoprostol in breast milk is negligible because its levels are so small and rapidly decreasing so the risks for the baby are minimal with the administration of a single dose. When administered for the treatment of postpartum haemorrhage Misoprostol has no contraindications to breastfeeding.

¨Patient Information Leaflet

Questions, Comments, Or Concerns?

We want to hear about it ...

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