FRONT SIDE

Miso-Fem

Misoprostol 200 mcg

Composition:

Each uncoated tablet contains:

Misoprostol .....200 mcg.

Excipients .....q.s.

Drug description:

Miso-Fem tablets contain 200 mcg of Misoprostol, a synthetic prostaglandin E1 (PGE1) analogue. It's a White to off-white, round, bevel edged, flat faced, uncoated tablets with "J"debossed above and "08" debossed below the score line on one side and plain on other side.

Clinical Pharmacology:

Pharmacodynamics:

Misoprostol belongs to a group of hormones called prostaglandins which can cause uterine contractions & opening (ripening) of the cervix and is widely used in obstetrics and gynaecology. Misoprostol also has antisecretory (inhibiting gastric acid secretion) and has mucosal protective properties. Misoprostol protects the gastroduodenal mucosa by inhibiting basal, stimulated and nocturnal acid secretion and by reducing the proteolytic activity of gastric fluid and increasing bicarbonate and mucus secretion.

Pharmacokinetics:

Misoprostol is readily absorbed, & undergoes rapid de-esterification to its free acid, if bound to plasma protein, & its metabolites include prostaglandin-F analogues. The compound is lipophilic methyl ester pro drug and is readily metabolized to the free acid, which is biologically active. When administered orally peak plasma concentration is attained within 30 minutes and rapidly declines by 120 minutes. 80% of the drug is excreted through renal route and 15% through faecal route.

Indications: Miso-Fem is in dicated for the:

-Prevention of postpartum haemorrhage

-Treatment of postpartum haemorrhage

-Treatment of incomplete abortion and missed miscarriage in the first trimester

-Treatment of duodenal ulcer and gastric ulcer and NSAID induced peptic ulcer

-Prophylaxis of NSAID induced peptic ulcers

-Cervical ripening

-Induction of labour (living or dead foetus)

Dosage and Administration:

Prevention of postpartum haemorrhage:

600 mcg orally administered immediately after the delivery of the baby and confirmation that all foetuses have been delivered (in case of multiple births).

Treatment of postpartum haemorrhage:

800mcg sublingually or 1000mcg administered rectally, significantly reduces the need for additional interventions.

Treatment of incomplete abortion and missed miscarriage in the first trimester:

800mcg administered vaginally or sublingually, and repeated after 24hours.

(Healthcare provider is advised to offer all women receiving medical management of miscarriage, pain relief, antibiotics and anti-emetics as needed.)

Treatment of duodenal ulcer, gastric ulcer and NSAID-induced peptic ulcer:

800mcg orally, taken daily in two or four divided doses with breakfast and /or each main meal and at bed time. In most patients, ulcers will be healed in 4weeks but treatment may be continued for up to 8weeks if required. If the ulcer relapses further treatment courses may be given.

Prophylaxis of NSAID induced peptic ulcer:

200mcg orally two to four times daily. Dosage should be individualised according to the clinical condition of each patient.

Cervical ripening:

For cervical priming prior to transcervical procedure; 400mcg vaginally or orally 3 hours before the procedure.

Induction of labour (living or dead foetus):

For living foetus: 25mcg intravaginally stat, then repeat every 3-6 hours up to 6 doses maximum. (Not to be used in patients with caesarean delivery or major uterine surgery).

For intrauterine foetal death (IUFD): of 13-17 weeks- 200mcg vaginally every 6 to 12 hours for a total of 4 doses. IUFD from 18-26 weeks: 100mcg vaginally every 6-12 hours for a total of 4 doses. IUFD beyond 26 weeks: for unripe cervix (Bishop score<6), vaginal misoprostol 25-50mcg every 4 hours-up to 6 doses; if cervix is ripe (Bishop score>6), use a first dose of 25-50mcg and subsequent doses should be doubled to 50-100mcg if the contractions are not effective. Maximum daily dosing is 600mcg. Repeat after 24 hours if expulsion has not occurred.

BACK SIDE

Precautions for use:

In twin or multiple pregnancies:

Miso-Fem should not be used to treat or prevent postpartum haemorrhage until after the delivery of all the newborns.

Breastfeeding:

Misoprostol levels in breast milk are immeasurable after 5hours of a single oral dose of 600mcg therefore when administered for postpartum haemorrhage, misoprostol has no breastfeeding contraindications. However, Misoprostol should not be continuously administered to nursing mothers for treating peptic ulcers because the continuous excretion of misoprostol in milk can cause diarrhoea in nursing infants.

Children:

Use of **Miso-Fem** in children has not yet been evaluated.

Contraindications:

Miso-Fem is contraindicated:

- In hypersensitivity to prostaglandins.
- Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass.
- To treat or prevent ulcers in pregnant women or women of child bearing potential.
- Chronic adrenal failure
- Haemorrhagic disorders or concurrent anticoagulant therapy
- Inherited porphyria
- If an Intrauterine device (IUD) is in place.

Drug Interactions:

Miso-Fem does not interfere with the beneficial effects of aspirin on signs and symptoms of rheumatoid arthritis. Miso-Fem does not exert clinically significant effects on the absorption, blood levels, and antiplatelet effects on therapeutic doses of aspirin. Miso-Fem has no clinically significant effect on the kinetics of diclofenac or ibuprofen. The most common side effect of Miso-Fem is diarrhoea and abdominal pain. These side effects may be increased if Miso-Fem is taken concurrently with antacids.

Side Effects:

- Patient may experience pain due to uterine contractions
- Gastrointestinal side effects like diarrhoea, abdominal pain, nausea, flatulence, dyspepsia, headache, vomiting, constipations, etc.
- Shivering and dizziness

Warnings:

The patient may require immediate medical attention if excessive bleeding or other adverse reactions occurs. Also the patients should be given instructions on what to do if cramps and gastrointestinal disturbances occur after administration of Miso-Fem. There may be increased risk of uterine tachysystole, uterine rupture, meconium passage, meconium staining of amniotic fluid, and caesarean delivery due to uterine hyper stimulation with the use of higher doses of Miso-Fem. It may cause diarrhoea and should not be co-administered with other drugs that cause diarrhoea (such as magnesium-containing antacids)

Adverse Reactions:

- Severe genital bleeding
- Shock
- Uterine rupture
- Severe pelvic pain

Consult your Doctor, Pharmacist, Nurse or other family provider for advice.

Overdosage:

The symptoms of a misoprostol overdose might include stomach upset, stomach pain, diarrhoea, drowsiness, tremor, seizures, difficulty in breathing, fever, low blood pressure, and irregular heartbeat. Symptoms should be treated with supportive therapy.

Storage:

Store at below 30°C away from direct light.

Keep out of reach of children.

dkt INTERNATIONAL INC

Manufactured by:
Naari Pharma Private Limited
Plot No. 14-16, 55-57, Sector-5, IIE,
Pantnagar, Rudrapur-263153,
Dist.-Udham Singh Nagar,
Uttarakhand-India

NAARI Celebrating women

Manufactured for:
NAARI PTE, Singapore.

C 100
M 100
Y 100
K 100
PANTONE 239 C
PANTONE COOL GREY 11 C

100 x 216 mm

100 x 216 mm

Leaflet : Miso-Fem		**Market : Rwanda**
Dimensions : 100 x 216 mm	**Font Color : Black**	
Font : Calibri	**Title: pt**	**Subtitle: 6.65 pt**
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