Miso-Fem®
(Misoprostol 200 mcg)

Composition:
Each uncoated tablet contains:
Misoprostol ........................................ 200 mcg.

Drug description:
Miso-Fem tablets contain 200 mcg of Misoprostol, a synthetic prostaglandin E1 (PGE1) analogue. Its a White to off-white, round, bevel edged, flat faced, uncoated tablets with “ST” debossed above and “20” debossed below the score line on one side and plain on other side.

Clinical Pharmacology:
Pharmacodynamics:
Miso-Fem belongs to a group of hormones called prostaglandins which can cause uterine contractions & opening (lacing) of the cervix and is widely used in abortions and miscarriages. Miso-Fem also has anti-secretory (inhibiting gastric acid secretion) and has muscular protective properties. Misoprostol protects the gastrointestinal mucosa by inhibiting basal, stimulated and mucosal acid secretion and by reducing the prostaglandin activity of gastric fluid and increasing bicarbonate and mucus secretion.

Pharmacokinetics:
Miso-Fem 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 a specific methyl ether prodrug and is readily metabolized to its free acid, which is biologically active. When administered orally peak plasma concentration is attained within 30 minutes and plasma half life is 20 minutes. 80% of the drug is excreted through renal route and 15% through faecal route.

Indications: Miso-Fem is indicated for:
- Prevention of postpartum haemorrhage
- Treatment of incomplete abortion and missed miscarriage in the first trimester
- Treatment of decidua ulcer and gastric ulcer and NSAI 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:
800 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 100mcg administered rectally significantly reduces the need for additional intervention.

Treatment of incomplete abortion and missed miscarriage in the first trimester:
800mcg administered vaginally or sublingually, and repeated after 24 hours.

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

Treatment of decidua ulcer gastric ulcer and NSAI induced peptic ulcer:
800mcg orally, taken daily in two or four divided doses with breakfast and/or main meals and at bedtime. In most patients, ulcers will be healed in 4 weeks but treatment may be continued for up to 6 weeks if required. If the ulcer relapses further treatment courses may be given.

Prophylaxis of NSAI 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 transvaginal procedure; 400mcg vaginally or orally 3 hours before the procedure.

Induction of labour (living or dead foetal):
For living foetus: 20mcg intravenously can be given, repeat every 3-6 hours up to 6 doses maximum. (Not to be used in patients with cesarean delivery or major uterine surgery).

For intrauterine fetal death (IUFD) of 13-17 weeks: 200mcg vaginally every 6 to 12 hours for a total of 4 doses. Full term 18-26 weeks: 100mcg vaginally every 6-12 hours for a total of 4 doses. IUFD beyond 26 weeks: for unripe cervix (Bishop score), vaginal misoprostol 5-10mcg every 4 hours up to 6 doses; if cervix is ripe (Bishop score), 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 600mg. Repeat after 24 hours if expulsion has not occurred.

Precautions for use:
- in two or multiple pregnancies:
- Miso-Fem should not be used to treat or prevent postpartum haemorrhage until after the delivery of all the newborns.
- Breastfeeding:
  Miso-Fem levels in breast milk are measurable after 8 hours 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 and nursing infants.
- Children:
  Use of Miso-Fem in children has not yet been evaluated.

Contraindications:
Miso-Fem is contraindicated:
- In hypersensitivity to prostaglandins.
- Cerebral angiography or suspected intracranial or subdural or epidural haemorrhage
- To treat or prevent abortion in pregnant women or women of childbearing potential.
- Chronic renal failure
- Haemorrhagic disorders or concomitant antibiotic therapy
- Hypertension

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 placebo effects on therapeutic doses of aspirin. Miso-Fem has no clinically significant effect on the kinetics of diazepam or iron. The most common side effect of Miso-Fem is diarrhea 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
- Gastrintestinal 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 occur. 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 tachyphylaxis, uterine rupture, meconium passage, maternal bleeding, meconium accretion, and caesarean delivery due to uterine hyperstimulation 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

Overdose:
The symptoms of a misoprostol overdose might include stomach upset, stomach pain, diarrhoea, dizziness, tachycardia, anxiety, difficulty in breathing, fever, low blood pressure, irregular heartbeat. Symptoms should be treated with supportive therapy.

Storage: Store at or below 30°C in a dry area. Keep out of reach of children.

Last revision date: 20 February, 2014

Manufactured by:
Jagannath Pharmaceuticals Ltd.,
Plot No. 16-16 and 55-57, Sector 5,
IIE, Patial Nagar, Rudrapur (U.G. Nagar),
Uttarakhand, India.

Manufactured for: NAARI, NAARI AG, Switzerland.

Imported and distributed by:
Deep K. Tipsy Foundation Nigeria,
Plot 4, Block E, Iloko Industrial Layout,
Oshodi-Appa Expressway, Lagos.
info@dkftipsy.org

31 October 2014 15:15:39
Composition:
Chaque comprimé non enrobé contient:
Misoprostol: 200 mcg.
Escarène: 4 mg.
Description du médicament:
Les comprimés de Misoprostol contiennent 200 mcg de Misoprostol, analogique synthétique de la prostaglandine F (PGF1) qui s'agit d'un composant d'une hormone entre le blanc et le blé cassé, rond, en bleu, plat, non enrobé et marqué "20" en haut et "4" en bas d'un trait d'une couche.

Pharmacocinétique:
Pharmacodynamique:
Le Misoprostol appartient à un groupe d'hormones dénommées prostaglandines qui peuvent causer des contractions et des ouvertures (maturations) du col de l'utérus et est largement utilisé en obstétrique et en gynécologie. Le Misoprostol possède également des propriétés anti-secretoriales (inhibition de la sécrétion acide gastrique) et de protection de la muqueuse gastrique contre le médicament. Le Misoprostol protège la muqueuse gastrique du dos hormonale en inhibant la sécrétion acide basale, stimulée et nocturne, en réduisant l'activité protéolytique du foie gastrique et en accroissant la sécrétion de la bicarbonatation de la muqueuse.

Indications: Miso-Fem est indiqué dans les cas suivants:
- Prévention de l'insuffisance postpartum
- Traitement de l'insuffisance endométriose
- Traitement de l'insuffisance utérine, de l'insuffisance gastrique et de l'insuffisance gastroduodénale
- Traitement des ANS
- Désenfroissement

Posologie et Administration:
Prévention de l'insuffisance postpartum:
50 mcg par voie orale immédiatement après l'accouchement et confirmation que tous les traits ont été accouchés (les cas de naissances multiples).
Traitement de l'insuffisance endométriose:
50 mcg par voie orale immédiatement après l'accouchement et confirmation que tous les traits ont été accouchés (les cas de naissances multiples).
Traitement de l'insuffisance utérine, de l'insuffisance gastrique et de l'insuffisance gastroduodénale:
50 mcg par voie orale immédiatement après l'accouchement et confirmation que tous les traits ont été accouchés (les cas de naissances multiples).

Interactions médicamenteuses:
Misoprostol entraine des effets secondaires sur l’insuffisance postpartum, les patients doivent être instruits de la nécessité de consulter un spécialiste en cas de symptômes suspects.

Effets secondaires:
Les patients doivent être informés des effets secondaires possibles et de la nécessité de consulter un spécialiste en cas de symptômes suspects.

Avis aux patients:
Les patients doivent être informés des effets secondaires possibles et de la nécessité de consulter un spécialiste en cas de symptômes suspects.

Importé et distribué par:
Deep K. Tyagi Foundation Nigeria, Plot 4, Block I, Isolo Industrial Layout, Oshodi-Appa Expressway, Lagos. info@dsfinigeria.org

Produit de:
Jagannath Pharmaceuticals Ltd., Plot N° 14-16 and 55-57, Sector 5, IIT, Pant Nagar, Rudrapur (U.S. Nagar), Uttarakhand, India.

Produit pour:
NAARI AG, Switzerland.

Date de dernière révision: février 2014

Misdem_leaflet
31 October 2014 15:15:45