DGF Drugfield **PHARMACEUTICALS LIMITED**

SUMMARY OF PRODUCT CHARACTERISTICS

Misoprostol Tablets

1. NAME OF THE MEDICINAL PRODUCT

Misoprostol (200mcg/Tablet) Tablet

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Misoprostol 200 microgram

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Tablets

4. Clinical particulars

4.1 Therapeutic indications

Misoprostol is indicated for the treatment of postpartum hemorrhage suspected to be due to uterine atony after vaginal delivery. Use of misoprostol for post-partum heamorrhage treatment is effective in reducing postpartum blood loss following vaginal delivery. A single dose of misoprostol has been shown to control active bleeding within 20 minutes of administration for approximately 90% of women in hospital setting. Misoprostol is also indicated for the healing of duodenal and gastric ulcer involving those induced by nonsteroidal anti- inflammatory drugs (NSAIDs).

4.2 Posology and method of administration

1) Postpartum hemorrhage
   The recommended regimen of postpartum hemorrhage is single dose of 800mcg Misoprostol sublingually(under the tonugue)
2) Treatment of benign gastric and duodenal ulceration including that associated with NSAIDs the usual dose by month is 800 micrograms daily in two or four divided doses with foods

<u>Method of administration</u>

Oral administration

4.3 Contraindications

Hypersenistivity to Misorostol, prostaglandins, or any component of the formulation. Misoprostol is contraindicated in pregnancy

4.4 Special warnings and precautions for use

- Misoprostol should not be used in pre-menopausal women unless the patient required nonsteroidal anti- inflammatory (NSAIDs) therapy and is at high risk of complications from NSAIDs- induced ulceration.
- Safety and efficacy have not been established in children< 18 years of age; use with caution in paints with renal impairment and the elderly.
- It should be used with caution in patients in whom hypotension might cause severe complications.

PREGNANCY AND LACTATION

Misoprostol is contraindicated in pregnant women and in women planning a pregnancy as it increases uterine tone and contractions in pregnancy which may cause partial or complete expulsions of the products of conception. It is not known if the active metabolite of misoprostol is excreted in breast milk therefore Misoprostol should not be administered during breast feeding.

4.5 Interaction with other medicinal products and other forms of interaction

- Antacids may diminish absorption(not clinically significant)
- Misoprostol peak serum concentrations may be decreased if taken with food(Not clinically significant)

4.6 Undesirable effects

Gastrointestinal system

Diarrhoea has been reported and is occasionally severe and prolonged and may require withdrawal of the drug. It can be minimized by using single doses not exceeding 200 micrograms with food and by voiding the use of predominantly magnesium containing antacids when an antacid is required abdominal pain with or without associated dyspepsia or diarrhea can follow Misoprostol therapy.

Female Reproductive System

Menorrhagia, vaginal bleeding and inter- menstrual bleeding have been reported in pre and post-menopausal women. Skin rashes has been reported.

4.7 Overdose

Symptoms include sedation, tremor, convulsion, dyspnea, abdominal pain, diarrhea, hypotension and bradycardia. In the event of over dosage symptomatic and supportive therapy should be given as appropriate. In clinical trials patients have tolerated 1200 microgram daily for three months without significant adverse effects

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Misoprostol is a synthetic prostaglandin E, analogue that replaces the protective prostaglandins consumed with prostaglandin- inhibiting therapies e.g nonsteroidal anti- inflammatory drugs. Misoprostol induces uterine contractions; it is commonly used for obstetric indications. Postpartum heamorrhage (PPH) is excessive bleeding following birth and occurs in 5-10% of deliveries.

5.2 Pharmacokinetic properties

Misoprostol is reported to be rapidly absorbed and metabolized to its active form (Misoprostol acid) after oral doses; peak plasma concentration of Misoprostol acid occur after about 15 to 30 minutes. Food reduces the rate but not the extent of absorption. Misoprostol acid is further metabolized by oxidation in a number of body organs and is excreted mainly in the urine. The plasma elimination half-life is reported to be between 20 and 40 minutes.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6. PHARMACEUTICALPARTICULAR

6.1 List of excipients

Sodium lauryl sulphate
Microcrystalline cellulose(ph 101)
Sodium starch glycolate

6.2 Incompatibilities

None have been reported or are known

6.2 Shelflife

3 years

6.3 Special precautions for storage

Store below 30^0C. Protect from light and moisture

6.4 Nature and contents of container and special equipment for use, administration or implantation

Misoprostol is available as 200mcg tablet presented in a blister pack of 3's and 10's.

6.5 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

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