Breeky® 200mcg Tablets

(Misoprostol)

INTRODUCTION:
Misoprostol oral tablets contain 200mcg of misoprostol, a synthetic prostaglandin E1 analog

COMPOSITION:
Each tablet contains:
Misoprostol dispersion USP
equivalent to Misoprostol.....200mcg

CLINICAL PHARMACOLOGY:
Misoprostol has both antisecretory (inhibiting gastric acid secretion) and mucosal protective properties. NSAIDs inhibit prostaglandin synthesis and a deficiency of prostaglandins within the gastric mucosa may lead to diminishing bicarbonate and mucus secretion and may contribute to the mucosal damage caused by these agents. Misoprostol can increase bicarbonate and mucus production, but this has been shown at doses 200mcg and above that are also antisecretory. It is therefore not possible to tell whether the ability of misoprostol to reduce the risk of gastric ulcer is the result of its antisecretory effect, its mucosal protective effect or both

MECHANISM OF ACTION:
Misoprostol belong to a group of hormones called prostaglandins which can cause uterine contractions and opening (ripening) of the cervix. Although prostaglandins are highly effective, their efficacy depends on number of prostaglandins receptors in the uterus and this varies according to the whether the women is pregnant and at what stage of pregnancy she is. At the end of pregnancy there are many receptors and a small dose of misoprostol leads to strong contractions

PHARMACOKINETICS:
Misoprostol is extensively absorbed and undergoes rapid de-esterification to its free acid, which is responsible for its clinical activity and unlike the parent compound is detectable in plasma

Misoprostol is rapidly absorbed after oral administration with a Tmax of misoprostol acid of 12 ± 3 minutes and a terminal half-life of 20-40 minutes

No accumulation of misoprostol acid was noted in multiple dose studies; plasma steady state was achieved within two days. Maximum plasma concentrations of misoprostol acid are diminished when the dose is taken with food and total availability of misoprostol acid is reduced by use of concomitant antacid
After oral administration of radiolabeled misoprostol, about 80% of detected radioactivity appears in urine. In patients with varying degrees of renal impairment showed an approximate doubling of T1/2, Cmax and AUC compared to normals, but no clear correlation between the degree of impairment and AUC. In elderly over 64 years of age, the AUC for misoprostol acid is increased. No routine dosage adjustment is recommended in older patients or patients with renal impairment, but dosage may need to be reduced if the usual dose is not tolerated

A lack of drug interaction with antipyrine and propranolol is shown when these drugs are used with misoprostol. Misoprostol does not effect the steady state pharmacokinetics of diazepam when used 2 hours apart. The serum protein binding of misoprostol acid is less than 90% and is concentration-independent in the therapeutic range

INDICATIONS:
Antiulcerant Indication:
Misoprostol is indicated for reducing the risk of NSAID (nonsteroidal anti-inflammatory drugs, including aspirin)-induced gastric ulcers in patients at high risk of complications from gastric ulcer, e.g., the elderly and patients with concomitant debilitating disease, as well as patients at high risk of developing gastric ulceration, such as patients with a history of ulcer. Misoprostol has not been shown to reduce the risk of duodenal ulcers in patients taking NSAIDs. Misoprostol should be taken for the duration of NSAID therapy. It had no effect, compared to placebo on gastrointestinal pain or discomfort associated with NSAID use

Gynecological Indication:
- In the prevention & treatment of Postpartum Hemorrhage (PPH)
- Labor Induction (in unfavorable cervical conditions)

DOSAGE AND ADMINISTRATION:
For Reducing the Risk of NSAID-induced Gastric Ulcers:
The recommended adult oral dose of misoprostol for reducing the risk of NSAID-induced gastric ulcers is 200mcg four times daily with food. Misoprostol should be taken for the duration of NSAID therapy as prescribed by the physician. Misoprostol should be taken with a meal and the last dose of the day should be at bedtime

Postpartum Hemorrhage (PPH):
- **Prohylaxis:** 600mcg orally or rectally after delivery (with in 1 minute)
- **Treatment:** 800mcg orally or sublingually (single dose); use caution if prophylactic dose already given

Induction of Labor:
25mcg vaginally every 4-6 hours
OR
25mcg orally every 2 hours

OR
As directed by the physician

ADVERSE EFFECTS:
The following have been reported as adverse events in subjects receiving misoprostol:

Gastrointestinal: GI disorders had the highest reported incidence of adverse events for patients receiving the preparation. It can cause more abdominal pain, diarrhea and other GI symptoms. The incidence of diarrhea can be minimized by administering it with food and by avoiding co-administration with magnesium containing antacids

Gynecological: Gynecological disorders such as spotting, cramps, hypermenorrhea, menstrual disorder and dysmenorrhea. Postmenopausal vaginal bleeding may be related to misoprostol administration

Elderly: Overall there were no significant differences in the safety profile in patients 65 years of age or older compared with younger patients

PRECAUTIONS AND WARNING:
Precaution should be taken in conditions where hypertension might precipitate severe complications (e.g. cerebrovascular and cardiovascular diseases)

CONTRAINDICATIONS:
Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs). Misoprostol should not be taken by anyone with a history of allergy to prostaglandins

DRUG-DRUG INTERACTION:
Misoprostol has not been shown to interfere with the beneficial effects of aspirin on signs and symptoms of rheumatoid arthritis. Misoprostol does not exert clinically significant effects on the absorption, blood levels and antiplatelet effects of therapeutic doses of aspirin. Misoprostol has no clinically significant effect on the kinetics of diclofenac or ibuprofen

USE IN PREGNANCY AND LACTATION:
Because of the abortifacient property of the misoprostol component, it is contraindicated in women who are pregnant. It should not be used in women of childbearing potential unless the patient requires nonsteroidal anti-inflammatory drug (NSAIDs) therapy and it is at high risk of developing complications from gastric or duodenal ulcers associated with the use of the NSAIDs

In such patients, misoprostol may be prescribed if the patient:
- Has had a negative serum pregnancy test within 2 weeks prior to beginning therapy
- Is capable of complying with effective contraceptive measures
- Has received both oral and written warnings of the hazards of misoprostol, the risk of possible contraception failure and the danger to other women of childbearing potential should the drug be taken by mistake
- Will begin misoprostol only on the second or third day of the next normal menstrual period

STABILITY:
See expiry on the pack

PRESENTATION:
Breeky® 200mcg tablets with cross scored line in pack of 10's

INSTRUCTIONS:
To be swallowed whole with water
Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

بریکی® ۲۰۰ مائیکروگرام ٹیبلٹ

(میسوپروسٹول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
ثابت ٹیبلٹ چبائے بغیر پانی سے نگل لیں
بچوں کی پہنچ سے دور رکھیں
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

P001240/S R.N-05/HA/05/16

220 mm

71 mm