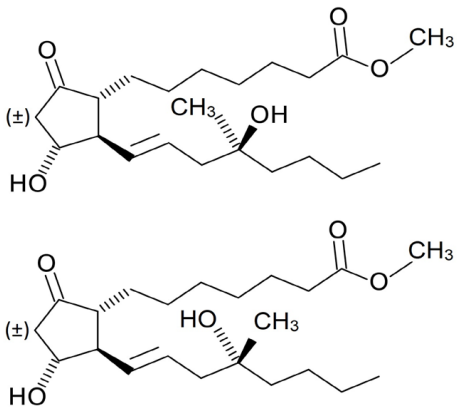
MISORT™ (Misoprostol) مِزورٹ

QUALITATIVE AND QUANTITATIVE COMPOSITION
MISORT Tablet 200 mcg
Each tablet contains:
Misoprostol as 1% HPMC Dispersion……200 mcg

WARNINGS
Misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.
Uterine rupture can occur when Misoprostol is administered in pregnant women to induce labor or to induce abortion. The risk of uterine rupture increases with advancing gestational ages and with prior uterine surgery, including cesarean delivery.
Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDS).
Patients must be advised of the abortifacient property and warned not to give the drug to others. Should not be used for reducing the risk of NSAID-induced ulcers in women of childbearing potential unless the patient is at high risk of complications from gastric ulcers associated with use of the NSAID, or is at high risk of developing gastric ulceration. 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 only on the second or third day of the next normal menstrual period

DESCRIPTION
MISORT tablet contains Misoprostol which is a synthetic prostaglandin E_1 analog. Misoprostol contains approximately equal amounts of the two diastereomers presented below with their enantiomers indicated by (±):



CLINICAL INFORMATION
Indications
MISORT (Misoprostol) is indicated for reducing the risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulcer, as well as patients at high risk of developing gastric ulceration.

Dosage and administration
Adult dosage
The recommended adult oral dose for reducing the risk of NSAID-induced gastric ulcers is 200 mcg four times daily with food. If this dose cannot be tolerated, a dose of 100 mcg can be used. Misoprostol should be taken for the duration of NSAID therapy as prescribed by the physician. Should be taken with a meal, and the last dose of the day should be at bedtime.
Pediatric dosage
Safety and effectiveness in pediatric patients have not been established.

Dosage adjustment
Renal impairment
Adjustment of the dosing schedule in renally impaired patients is not routinely needed, but dosage can be reduced if the 200 mcg dose is not tolerated.

Contraindications
- Should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs
- Should not be taken by anyone with a history of allergy to prostaglandins

Warning and Precautions
- Caution should be employed when administering Misoprostol to patients with pre-existing cardiovascular disease
- Women of childbearing potential using Misoprostol to decrease the risk of NSAID-induced ulcers should be told that they must not be pregnant when Misoprostol therapy is initiated, and that they must use an effective contraception method while taking Misoprostol
- May cause birth defects, abortion (sometimes incomplete), premature labor or rupture of the uterus if given to pregnant women

Drug Interactions
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.
Prostaglandins such as Misoprostol may augment the activity of oxytocic agents, especially when given less than 4 hours prior to initiating oxytocin treatment. Concomitant use is not recommended.

Pregnancy and Breast Feeding
Pregnancy Category X: Caution should be exercised when Misoprostol is administered to a nursing woman.

Effects on ability to drive and use machines
Dizziness can occur after taking Misoprostol. Be cautious when driving or operating machinery.

Adverse Reactions
- ***Body as a whole:*** aches/pains, asthenia, fatigue, fever, chills, rigors, weight changes
- ***Skin:*** rash, dermatitis, alopecia, pallor, breast pain
- Respiratory: upper respiratory tract infection, bronchitis, bronchospasm, dyspnea, pneumonia, epistaxis
- ***Cardiovascular:*** chest pain, edema, diaphoresis, hypotension, hypertension, arrhythmia, phlebitis, increased cardiac enzymes, syncope, myocardial infarction (some fatal), thromboembolic events (e.g., pulmonary embolism, arterial thrombosis, and CVA)
- ***Gastrointestinal:*** GI bleeding, GI inflammation / infection, rectal disorder, abnormal hepatobiliary function, gingivitis, reflux, dysphagia, amylase increase
- ***Hypersensitivity:*** anaphylactic reaction
- ***Metabolic:*** glycosuria, gout, increased nitrogen, increased alkaline phosphatase
- ***Genitourinary:*** polyuria, dysuria, hematuria, urinary tract infection
- ***Nervous system/Psychiatric:*** anxiety, change in appetite, depression, drowsiness, dizziness, thirst, impotence, loss of libido, sweating increase, neuropathy, neurosis, confusion
- ***Musculoskeletal:*** arthralgia, myalgia, muscle cramps, stiffness, back pain

Overdose
The toxic dose in humans has not been determined. Cumulative total daily doses of 1600 mcg have been tolerated, with only symptoms of gastrointestinal discomfort.

PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group
Anti ulcer agents

Mechanism of Action
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 200 mcg 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.

Pharmacokinetic properties
Absorption
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.

Distribution
Rapidly absorbed after oral administration with a T_{max} of Misoprostol acid of 12 ± 3 minutes. The serum protein binding of Misoprostol acid is less than 90% and is concentration-independent in the therapeutic range.

Excretion
Terminal half-life of 20 - 40 minutes.

PHARMACEUTICAL INFORMATION
Shelf life
2 Years

Instructions:
Do not store above 30°C.
Protect from sunlight, moisture and heat.
Keep all medicine out of sight and reach of children.

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔
دوا کو سورج کی روشنی، نمی اور گرمی سے بچائیں۔
تمام ادویات کو بچوں کی نظر اور پہنچ سے دور رکھیں۔

Nature and contents of container
Misort Tablet 200 mcg are available in a blister pack of 28's.

MANUFACTURED BY:
ASPIN
An OBS Group Company
Aspin Pharma (Pvt.) Ltd.
Plot No. 10 & 25, Sector No. 20,
Korangi Industrial Area, Karachi-74900, Pakistan.
www.aspin.com.pk

REVISION DATE
March 2022