Isovent®

Misoprostol BP

COMPOSITION
Isovent® 100 tablet: Each tablet contains 100 micrograms of Misoprostol BP.
Isovent® 200 tablet: Each tablet contains 200 micrograms of Misoprostol BP.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Isovent® (Misoprostol) is an analogue of naturally occurring prostaglandin E_1 which promotes peptic ulcer healing and symptomatic relief. **Isovent®** protects the gastroduodenal mucosa by inhibiting basal, stimulated and nocturnal acid secretion and by reducing the volume of gastric secretions, the proteolytic activity of the gastric fluid, and increasing bicarbonate and mucus secretion.
Being an analogue of prostaglandin E_1, Misoprostol has excellent uterotonic effect. So in many regions it is widely used in obstetrics and gynaecology. Like other uterotonics (e.g.oxytocin, ergometrine, syntometrine) Misoprostol causes the uterus to contract, and thus can reduce postpartum bleeding.
Pharmacokinetic properties
Isovent® is rapidly absorbed following oral administration, with peak plasma levels of the active metabolite (misoprostol acid) occurring after about 30 minutes. The plasma elimination half-life of misoprostol acid is 20-40 minutes. No accumulation of misoprostol acid in plasma occurs after repeated dosing of 400 micrograms twice daily.

THERAPEUTIC INDICATIONS
Isovent® is indicated for –
The healing of duodenal ulcer and gastric ulcer including those induced by nonsteroidal anti-inflammatory drugs (NSAID) in arthritic patients at risk, whilst continuing their NSAID therapy.
In addition, **Isovent®** can be used for the prophylaxis of NSAID-induced ulcers. Post Partum hemorrhage.

DOSAGE AND ADMINISTRATION
Adults
Healing of duodenal ulcer, gastric ulcer and NSAID-induced peptic ulcer: 800 micrograms daily in two or four divided doses taken with breakfast and / or each main meal and at bed time. Treatment should be given initially for at least 4 weeks even if symptomatic relief has been achieved sooner. In most patients ulcers will be healed in 4 weeks but treatment may be continued for up to 8 weeks if required. If the ulcer relapses further treatment courses may be given.

Prophylaxis of NSAID-induced peptic ulcer: 200 micrograms twice daily, three times daily or four times daily. Treatment can be continued as required. Dosage should be individualised according to the clinical condition of each patient.

Prevention of Post Partum Hemorrhage: Several clinical studies have suggested that 400 to 600 mcg of Misoprostol (administered orally) is as effective in reducing postpartum hemorrhage as oxytocin or syntometrine. Potency of Misoprostol compared to ergometrine, syntometrine is a subject of interest. Some times it has been used along with oxytocin/ ergometrine.

Elderly
The usual dosage may be used.
Renal impairment: Available evidence indicates that no adjustment of dosage is necessary in patients with renal impairment.
Hepatic impairment: Isovent® is metabolised by fatty acid oxidising systems present in organs throughout the body. Its metabolism and plasma levels are therefore unlikely to be affected markedly in patients with hepatic impairment.
Children
Use of Misoprostol in children has not yet been evaluated in the treatment of peptic ulceration or NSAID-induced peptic ulcer disease.

CONTRAINDICATIONS
In pregnancy.
Also contraindicated in patients with a known allergy to prostaglandins.

UNDESIRABLE EFFECTS
Gastrointestinal system: Diarrhoea has been reported and is occasionally severe and prolonged and may require withdrawal of the drug. It can be minimised by using single doses not exceeding 200 micrograms with food and by avoiding the use of predominantly magnesium containing antacids when an antacid is required.
Abdominal pain with or without associated dyspepsia or diarrhoea can follow misoprostol therapy.
Other gastrointestinal adverse effects reported include dyspepsia, flatulence, nausea and vomiting.

Female reproductive system: Menorrhagia, vaginal bleeding and intermenstrual bleeding have been reported in pre-and post-menopausal women.

Other adverse events: Skin rashes have been reported. Dizziness has been infrequently reported. The pattern of adverse events associated with Misprostol is similar when an NSAID is given concomitantly.
A number of side effects have been reported in clinical studies or in the literature following use of misoprostol for non-approved indications. These include abnormal uterine contractions, uterine haemorrhage, retained placenta, amniotic fluid embolism, incomplete abortion and premature birth.

DRUG INTERACTION
Misoprostol is predominantly metabolised via fatty acid oxidising systems and has shown no adverse effect on the hepatic microsomal mixed function oxidase (P450) enzyme system. In specific studies no clinically significant pharmacokinetic interaction has been demonstrated with antipyrine, diazepam and propranolol. In extensive clinical studies no drug interactions have been attributed to Misoprostol. Additional evidence shows no clinically important pharmacokinetic or pharmacodynamic interaction with nonsteroidal anti-inflammatory drugs including aspirin, diclofenac and ibuprofen.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Warnings
Use in pre-menopausal women: Misoprostol should not be used in pre-menopausal women unless the patient requires Nonsteroidal anti-inflammatory (NSAID) therapy and is at high risk of complications from NSAID-induced ulceration.
In such patients it is advised that Misoprostol should only be used if the patient:
Takes effective contraceptive measures
Has been advised of the risks of taking Misoprostol if pregnant. If pregnancy is suspected the product should be discontinued.

Precautions
The results of clinical studies indicate that Misoprostol does not produce hypotension at dosages effective in promoting the healing of gastric and duodenal ulcers. Nevertheless, Misoprostol should be used with caution in the presence of disease states where hypotension might precipitate severe complications, e.g., cerebrovascular disease, coronary artery disease or severe peripheral vascular disease including hypertension.
There is no evidence that Misoprostol has adverse effects on glucose metabolism in human volunteers or patients with diabetes mellitus.

OVERDOSE
Intensification of pharmacological effects may occur with overdose. In the event of overdosage symptomatic and supportive therapy should be given as appropriate. In clinical trials patients have tolerated 1200 micrograms daily for three months without significant adverse effects.

PREGNANCY AND LACTATION
Pregnancy
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 expulsion of the products of conception. Use in pregnancy has been associated with birth defects.

Lactation
It is not known if the active metabolite of Misoprostol is excreted in breast milk; therefore Misoprostol should not be administered during breast feeding.

STORAGE CONDITION
Store below 25°C. Protect from light & moisture. Keep out of children's reach.

HOW SUPPLIED
Isovent® 100 Tablet: Box containing 1x10 / 2x10 / 3x10 / 5x10 / 10x10 tablets in blister pack.
Isovent® 200 Tablet: Box containing 1x10 / 2x10 / 3x10 / 5x10 / 10x10 tablets in blister pack.

SQUARE