PRODUCT LITERATURE

GASTRICON TABLET
Each tablet contains:
Magnesium Hydroxide BP 400mg
Aluminium Hydroxide BP 400mg
Dimethicone USP 25mg

Preservatives
Sodium Benzoate BP 0.1%w/w

GASTRICON SUSPENSION
Each 5 ml contains:
Magnesium Hydroxide BP 400mg
Aluminium Hydroxide BP 400mg
Dimethicone USP 25mg

Preservatives
Methyl Paraben 0.1%w/v
Propyl Paraben 0.01%w/v

Product Description
Tablet: Round, yellow coloured tablet.
Suspension: Yellow coloured viscous suspension with peppermint odour and minty sweet taste.

Pharmacodynamics / Pharmacokinetics
Mechanism of action/Effect:

Antacid - These medications react chemically to neutralize or buffer existing quantities of stomach acid but have no direct effect on its output. This action results in increased pH value of stomach contents, thus providing relief of hyperacidity symptoms. Also, these medications reduce acid concentration within the lumen of the esophagus. This causes an increase in intraesophageal pH and a decrease in pepsin activity.

Antacids may increase lower esophageal sphincter (LES) pressure. Aluminum-containing antacids have a cytoprotective effect on the gastric mucosa that may be associated with the stimulation of prostaglandin secretion, thus providing protection against mucosal necrosis and hemorrhage caused by corrosive agents, such as aspirin and ethanol.

Absorption:
Aluminum - containing - Small amounts of the aluminum in aluminum hydroxide are absorbed from the intestine.

Magnesium - containing - Approximately 10% of the magnesium in magnesium hydroxide (magnesia) is absorbed from the intestine.

Onset and duration of action
Onset of action is dependent upon the ability of the antacid to solubilize in the stomach and react with the hydrochloric acid. The poorly soluble antacids (e.g., magnesium trisilicate) will thus react more slowly with hydrochloric acid than will the more soluble ones. In most cases with slow-acting antacids, the onset of action is delayed and may not take place if gastric emptying is rapid.

Duration of action is determined primarily by gastric emptying time. Depending on the kind of antacid used, the duration of action in fasting patients may range from 20 to 60 minutes.
However, when the antacid is given 1 hour after meals, the acid-neutralizing effect may be prolonged up to 3 hours.

Antacid	Onset of action	Duration of action
Aluminum Hydroxide	Slow	Prolonged
Magnesium Hydroxide	Fast	Short

Elimination:
Renal and fecal; 15 to 30% of the salts formed are absorbed and are then excreted by the kidneys.

Indication:
For the management of symptoms associated with gastric hyperacidity.

Recommended Dose:
To be given 20 min – 1 hour after meals and at bedtime.
Tablet: Adult: 1 - 2 tablet
Children (6 - 12 years): 1/2 - 1 tablet

Suspension: To be given 20 min – 1 hour after meals and at bedtime:
Adult: 5 ml - 10 ml
Children (6 - 12 years): 2.5 ml - 5 ml

Route of Administration
Oral

Contraindications
Except under special circumstances, these medications should not be used when the following medical problems exist:

»***Intestinal obstruction***
» ***Renal function impairment, severe***
(increased risk of hypermagnesemia)

Risk-benefit should be considered when the following medical problems exist:
»***Alzheimer"s disease***
(may be exacerbated)
»***Appendicitis***, or symptoms of
(may complicate existing condition; laxative or constipating effects may increase danger of perforation or rupture)
Bleeding, gastrointestinal or rectal, undiagnosed
(condition may be exacerbated)
Colitis, ulcerative
(may be aggravated by laxative effect of magnesium-containing antacids)
Colostomy or
Diverticulitis or
» ***Ileostomy***
(increased risk of fluid or electrolyte imbalance)
» ***Constipation or***
» ***Fecal impaction***
(may be exacerbated)
Diarrhea, chronic
(possible increased danger of phosphate depletion with aluminum-containing antacids)
(possible increased laxative effect with magnesium-containing antacids)
» ***Gastric outlet obstruction***
»***Hemorrhoids***
(may be aggravated)
» ***Renal function impairment***
(possible increased risk of aluminum toxicity to brain tissue, bone, and parathyroid glands; possible onset of the neurological syndrome - dialysis dementia - in dialysis patients with long-term use of aluminum-containing antacids)
Sensitivity to aluminum-, calcium-, magnesium-, simethicone-, or sodium bicarbonate – containing medications

Warnings and Precautions:
Pediatrics
Antacids should not be given to young children (up to 6 years of age) unless prescribed by a physician. Since children are not usually able to describe their symptoms precisely, proper diagnosis should precede the use of an antacid. This will avoid the complication of an existing condition (e.g., appendicitis) or the appearance of severe adverse effects.

Use of magnesium-containing antacids is contraindicated in very young children because there is a risk of hypermagnesemia, especially in dehydrated children or children with renal failure.

Use of aluminum-containing antacids is contraindicated in very young children because there is a risk of aluminum toxicity, especially in dehydrated infants and children or infants and children with renal failure.

Geriatrics
Metabolic bone disease commonly seen in the elderly may be aggravated by the phosphorus depletion, hypercalciuria, and inhibition of absorption of intestinal fluoride caused by the chronic use of aluminum-containing antacids. Also, elderly patients are more likely to have age-related renal function impairment, which may lead to aluminum retention.
Although it is not known whether high intake of aluminum leads to Alzheimer"s disease, the use of aluminum-containing antacids in Alzheimer"s patients is not generally recommended. Research suggests that aluminum may contribute to the diseases development since it has been found to concentrate in neurofibrillary tangles in brain tissue.

Interactions with Other Medicament:
Acidifiers, urinary, such as:
Ammonium chloride
Ascorbic acid
Potassium or sodium phosphates
Racemethionine
(antacids may alkalinize the urine and counteract the effect of urinary acidifiers; frequent use of antacids, especially in high doses, is best avoided by patients receiving therapy to acidify the urine)

Amphetamines or Quinidine
(urinary excretion may be inhibited when these medications are used concurrently with antacids in doses that cause the urine to become alkaline, possibly resulting in toxicity; dosage adjustment may be needed when therapy with these antacids is initiated or discontinued or if dosage is changed)

Anticholinergics or other medications with anticholinergic activity
(concurrent use with antacids may decrease absorption, reducing the effectiveness of anticholinergics; doses of these medications should be spaced 1 hour apart from doses of antacids)
(urinary excretion may be delayed by alkalinization of the urine, thus potentiating the side effects of the anticholinergic)
(concurrent use with magnesium-containing antacids may result in binding of magnesium; patients should be advised not to take these medications within 1 hour of cellulose sodium phosphate)

Chenodiol
(concurrent use with aluminum-containing antacids may result in binding of chenodiol, thus decreasing its absorption)

Citrates
(concurrent use with antacids containing aluminum, calcium carbonates, magaldrate, or sodium bicarbonate may result in systemic alkalosis)
(concurrent use of aluminum-containing antacids and magaldrate with citrate salts can increase aluminum absorption, possibly resulting in acute aluminum toxicity, especially in patients with renal insufficiency)
Digitalis glycosides
(concurrent use with aluminum- and magnesium-containing antacids may inhibit absorption, possibly decreasing plasma concentrations of digitalis glycosides; although actual clinical importance of this interaction has not been established, it is recommended that doses of antacids and digitalis glycosides be separated by several hours)
Enteric-coated medications, such as bisacodyl
(concurrent administration of antacids with enteric-coated medications may cause the enteric coating to dissolve too rapidly, resulting in gastric or duodenal irritation)

»Fluoroquinolones
(alkalinization of the urine may reduce the solubility of ciprofloxacin and norfloxacin in the urine, especially when the urinary pH exceeds 7.0; if antacids and one of these medications are used concurrently, patients should be observed for signs of crystalluria and nephrotoxicity)

(aluminum- and magnesium-containing antacids may reduce absorption of fluoroquinolones, resulting in lower serum and urine concentrations of these medications; therefore, concurrent use is not recommended; however, if aluminum- and magnesium-containing antacids must be used concurrently with these medications, it is recommended that enoxacin be taken at least 2 hours before or 8 hours after the antacid; ciprofloxacin and lomefloxacin should be taken at least 2 hours before or 6 hours after the antacid; and norfloxacin and ofloxacin should be taken at least 2 hours before or after the antacid)

Folic acid
(prolonged use of aluminum- and/or magnesium-containing antacids may decrease folic acid absorption by raising the pH of the small intestine; patients should be advised to take antacids at least 2 hours after folic acid)

Histamine H_2 -receptor antagonists
(concurrent use with antacids may be indicated in the treatment of peptic ulcer to relieve pain; however, simultaneous administration of medium to high doses [80 mmol to 150 mmol] of antacids is not recommended since absorption of histamine H_2 -receptor antagonists may be decreased; patients should be advised not to take any antacids within 1/2 to 1 hour of histamine H_2 -receptor antagonists)

Iron preparations, oral
(absorption may be de creased when these preparations are used concurrently with magnesium Trisilicate or antacids containing carbonate; spacing the doses of the iron preparation as far as possible from doses of the antacid is recommended)

» Isoniazid, oral
(concurrent use with aluminum-containing antacids may delay and decrease absorption of oral isoniazid; concurrent use should be avoided or the patient should be advised to take oral isoniazid at least 1 hour before the antacid)

» Ketoconazole
(antacids may cause increased gastrointestinal pH; concurrent administration with antacids may result in a marked reduction in absorption of ketoconazole; patients should be advised to take antacids at least 3 hours after ketoconazole)

»Mecamylamine
(alkalinization of th e urine may slow excretion and prolong the effects of mecamylamine; concurrent use is not recommended)

» Methenamine
(concurrent use with antacids that cause the urine to become alkaline may reduce the effectiveness of methenamine by inhibiting its conversion to formaldehyde; concurrent use is not recommended)

Misoprostol
(concurrent use with magnesium-containing antacids may aggravate misoprostol-induced diarrhea)

Pancrelipase
(concurrent administration of antacids may be required to prevent inactivation of pancrelipase [except enteric-coated dosage forms] by gastric pepsin and acid pH; however, calcium carbonate - and/or magnesium-containing antacids are not recommended since they may decrease the effectiveness of pancrelipase)

Penicillamine
(absorption may be reduced when penicillamine is administered concurrently with aluminum- or magnesium-containing antacids; although more studies are needed to establish the significance of this interaction, it is recommended that doses of antacids and penicillamine be separated by 2 hours)

Phenothiazines, especially chlorpromazine, oral
(absorption may be inhibited when these medications are used concurrently with aluminum- or magnesium-containing antacids; although more studies are needed to establish the significance of this interaction, simultaneous administration should be avoided)

Phenytoin
(concurrent use with aluminum-, magnesium-, and/or calcium carbonate - containing antacids may decrease absorption of phenytoin, thus reducing serum phenytoin concentrations; although more studies are needed to establish the significance of this interaction, it is recommended that doses of antacids and phenytoin be separated by about 2 to 3 hours)

Phosphates, oral
(concurrent use with aluminum- or magnesium-containing antacids may bind the phosphate and prevent its absorption)

Quinine
(concurrent use with aluminum-containing antacids may decrease or delay the absorption of quinine)

Salicylates
(alkalinization of the urine may increase renal salicylate excretion and lower serum salicylate levels; dosage adjustments of salicylates may be necessary when chronic high-dose antacid therapy is started or stopped, especially in patients receiving large doses of the salicylate, such as patients with rheumatoid arthritis or rheumatic fever)

Sodium fluoride
(concurrent use with aluminum hydroxide may decrease absorption and increase fecal excretion of fluoride)

»Sodium polystyrene sulfonate resin (SPSR)
(neutralization of gastric acid may be impaired when SPSR is used concurrently with calcium- or magnesium-containing antacids, possibly resulting in systemic alkalosis; concurrent use is not recommended)

Sucralfate
(concurrent use with antacids may be indicated in the treatment of duodenal ulcer to relieve pain; however, simultaneous administration is not recommended since antacids may interfere with binding of sucralfate to the mucosa; patients should be advised not to take any antacids within 1/2 hour before or after sucralfate; concurrent use with aluminum-containing antacids may cause aluminum toxicity in patients with chronic renal failure)

»Tetracyclines, oral
(absorption may be decreased when oral tetracyclines are used concurrently with antacids because of possible formation of nonabsorbable complexes and/or increase in intragastric pH; patients should be advised not to take antacids within 3 to 4 hours of tetracyclines)
Vitamin D, including calcifediol and calcitriol
(concurrent use with magnesium-containing antacids may result in hypermagnesemia, especially in patients with chronic renal failure)

Pregnancy and Lactation:
Pregnancy:
Antacids are generally considered safe as long as chronic high doses are avoided.
Adequate and well-controlled studies in humans have not been done; however, there have been reports of antacids causing such adverse effects as hypercalcemia, hypomagnesemia, hypermagnesemia, and increased tendon reflexes in fetuses and/or neonates whose mothers were chronic users of aluminum-, calcium-, and/or magnesium-containing antacids, especially in high doses.

Studies have not been done in animals.

Breast-feeding
Problems in humans have not been documented; although some aluminum, calcium, and magnesium may be distributed into breast milk, the concentration is not great enough to produce an effect in the neonate.

Side Effects
Medical attention needed
With long-term use in chronic renal failure in dialysis patients
Neurotoxicity (mood or mental changes)

With large doses
Fecal impaction (continuing severe constipation)

Osteomalacia and osteoporosis due to phosphate depletion (bone pain; swelling of wrists or ankles)

With prolonged use or large doses
Phosphorus depletion syndrome (continuing feeling of discomfort; continuing loss of appetite; muscle weakness; unusual weight loss)

With prolonged use or large doses and/or in renal disease
Hypomagnesaemia or other electrolyte imbalance (dizziness or light-headedness; irregular heartbeat;
mood or mental changes; unusual tiredness or weakness)

Symptoms and Treatment of Overdose
None

Packing:
Tablet: Packed in plastic container of 30's tablet.
Suspension: Packed in plastic container of 120 ml.

Pharmaceutical Precautions
Store below 30°C in a dry place, protected from direct light.
Keep away from reach of children.

Expiry:
Tablet: 3 years from date of manufacture
Suspension: 2 years from date of manufacture

Name and Address of Product Registration Holder/ Distributor:
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Lot 10 & 11, PERDA Industrial Park,
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