1. NAME OF THE MEDICAL PRODUCT

Milk of Magnesia Saline Laxative

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 mL serving contains:

1200mg of Magnesium hydroxide

Q.S. of purified water and Sodium hypochlorite as excipients

3. PHARACEUTICAL FORM

Liquid

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Milk of Magnesia is indicated for:

An over-the-counter remedy for treating occasional constipation (irregularity), heartburn, sour (upset) stomach, and usually produces a bowel movement in ½ to 6 hours of use.

4.2. Posology and method of administration

Milk of Magnesia is administered orally and should be taken following the dosage table below.

Adults and children 12 years and older	2 to 4 tablespoonfuls (TBSP)
Children 6 to 11 years	1 to 2 tablespoonfuls (TBSP)
Children under 6 years	Ask a doctor

Milk of Magnesia should be taken with the following directions:

- Shake the bottle well before use
- Do not exceed the maximum daily dose in a 24-hour period
- Dose may be taken once a day preferable at bedtime, in divided doses, or as directed by a doctor
- Drink a full glass (8 oz) of liquid with each dose

4.3. Contraindications

Milk of Magnesia (Magnesium hydroxide) is occasionally contraindicated in patients with colostomy, diverticulitis, or ileostomy because it increases the risk of developing electrolyte imbalance. The laxative effects of magnesium hydroxide can aggravate ulcerative colitis; use in these patients is relatively contraindicated. Patients with fecal impaction, GI obstruction, ileus, hemorrhoids, or undiagnosed rectal or GI bleeding should receive magnesium hydroxide with

caution; it is possible that these conditions could be aggravated, or the patient could develop sepsis, peritonitis, or ischemic bowel.

Avoid the use of magnesium hydroxide in patients with chronic diarrhea.

Magnesium hydroxide should be used cautiously in patients with renal impairment or renal disease because of the increased risk of developing hypermagnesemia and magnesium toxicity. Magnesium hydroxide should not be used in patients with renal failure unless their serum magnesium levels are closely monitored.

4.4. Special warnings and precautions for use

Consult a doctor before use if you have any one of the following:

- Kidney disease
- A magnesium-restricted diet
- Stomach pain, nausea, or vomiting
- A sudden change in bowel habits that lasts over 14 days
- Ask a doctor or pharmacist before us if you are taking a prescription drug. Milk of magnesia may interact with certain drugs (see contraindications section)

4.5. Interaction with other medicinal products and other forms of interaction

Abacavir; Dolutegravir; Lamivudine: (Moderate) Administer dolutegravir 2 hours before or 6 hours after taking cation-containing gastrointestinal medications such as magnesium hydroxide. The chemical structure of these GI drugs that contain polyvalent cations, such as magnesium hydroxide, can bind dolutegravir in the GI tract. Taking these drugs simultaneously may result in reduced bioavailability of dolutegravir.

Acalabrutinib: (Moderate) Separate the administration of acalabrutinib capsules and antacids by at least 2 hours if these agents are used together. Acalabrutinib capsules solubility decreases with increasing pH values; therefore, coadministration may result in decreased acalabrutinib exposure and effectiveness. In healthy subjects, the AUC of acalabrutinib was decreased by 53% when acalabrutinib was coadministered with another antacid.

Acetaminophen: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Aspirin, ASA; Caffeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Aspirin: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Aspirin; Diphenhydramine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Caffeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Caffeine; Dihydrocodeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Caffeine; Pyrilamine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Chlorpheniramine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Chlorpheniramine; Dextromethorphan: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Chlorpheniramine; Dextromethorphan; Phenylephrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Chlorpheniramine; Dextromethorphan; Pseudoephedrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Chlorpheniramine; Phenylephrine : (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Codeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan; Doxylamine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan; Guaifenesin; Phenylephrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan; Guaifenesin; Pseudoephedrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan; Phenylephrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dextromethorphan; Pseudoephedrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Dichloralphenazone; Isometheptene: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Diphenhydramine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Guaifenesin; Phenylephrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Hydrocodone: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected. (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Acetaminophen; Ibuprofen: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Oxycodone: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Pamabrom; Pyrilamine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Pentazocine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acetaminophen; Pseudoephedrine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Acidifying Agents: (Major) Aluminum hydroxide and magnesium hydroxide (as well as other antacids, i.e. aluminum hydroxide; magnesium carbonate, aluminum hydroxide; magaldrate; magnesium hydroxide, and aluminum hydroxide; magnesium trisilicate) may interact with urinary acidifiers by alkalinizing the urine. Frequent use of these high dose antacids should be avoided in patients receiving urinary acidifiers.

Amphetamines: (Minor) Monitor for an increase in amphetamine-related adverse effects during concomitant antacid use. Increasing gastric or urine pH may increase amphetamine exposure and the risk for side effects in some patients. As antacids have rarely been observed to increase gastric or urinary pH above 6.5, antacid-related pH changes may be insufficient to warrant clinical concern in most patients.

Anticholinergics: (Moderate) Antacids may inhibit the oral absorption of anticholinergics. Simultaneous oral administration should be avoided when feasible; separate dosing by at least 2 hours to limit an interaction.

Ascorbic Acid, Vitamin C: (Minor) Because antacids can alkalinize the urine, they can interact with urinary acidifiers, such as ascorbic acid. Frequent use of high doses of antacids should be avoided by patients receiving urinary acidifiers.

Atazanavir: (Major) It is recommended that antacids not be given at the some time as atazanavir because of potential interference with absorption of atazanavir. Separate the administration of atazanavir and antacids to avoid the potential for interaction; give atazanavir 2 hours before or 1 hour after the antacid.

Atazanavir; Cobicistat: (Major) It is recommended that antacids not be given at the some time as atazanavir because of potential interference with absorption of atazanavir. Separate the administration of atazanavir and antacids to avoid the potential for interaction; give atazanavir 2 hours before or 1 hour after the antacid.

Atorvastatin; Ezetimibe: (Minor) Antacids may decrease the peak plasma concentration (Cmax) of total ezetimibe by 30%. The effect of the antacids in this regard is not expected to have a significant effect on the ability of ezetimibe to lower cholesterol. However, to limit any potential interaction, it would be prudent to administer ezetimibe at least 1 hour before or 2 hours after administering antacids.

Atropine; Benzoic Acid; Hyoscyamine; Methenamine; Methylene Blue; Phenyl Salicylate: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness

of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Atropine; Difenoxin: (Moderate) Diphenoxylate can decrease GI motility. Drugs used to treat constipation, such as laxatives, would counteract the effect of antidiarrheals. In general, it would be illogical to concurrently administer these drugs at the same time. If an antidiarrheal medication is needed, it would be wise to temporarily discontinue use of agents with laxative effects.

Azithromycin: (Moderate) Separate administration of immediate-release azithromycin and aluminum- and magnesium-containing antacids by 2 hours. Coadministration may decrease the absorption of azithromycin which may decrease its efficacy. The extended-release suspension may be taken without regard to antacids containing aluminum or magnesium.

Baloxavir Marboxil: (Major) Do not administer baloxavir with products that contain magnesium hydroxide. Polyvalent cations, such as magnesium, can chelate with baloxavir, reducing its absorption.

Bempedoic Acid; Ezetimibe: (Minor) Antacids may decrease the peak plasma concentration (Cmax) of total ezetimibe by 30%. The effect of the antacids in this regard is not expected to have a significant effect on the ability of ezetimibe to lower cholesterol. However, to limit any potential interaction, it would be prudent to administer ezetimibe at least 1 hour before or 2 hours after administering antacids.

Benzhydrocodone; Acetaminophen: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Benzoic Acid; Hyoscyamine; Methenamine; Methylene Blue; Phenyl Salicylate: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Bictegravir; Emtricitabine; Tenofovir Alafenamide: (Moderate) Administer bictegravir on an empty stomach 2 hours before or 6 hours after taking antacids containing aluminum or magnesium. Routine administration of bictegravir simultaneously with, or 2 hours after, antacids containing aluminum or magnesium is not recommended as the bioavailability of bictegravir may be reduced. In drug interaction studies, simultaneous administration of bictegravir and antacids under fasted and fed conditions decreased the mean AUC of bictegravir by approximately 79% and 47%, respectively.

Bisacodyl: (Minor) The concomitant use of bisacodyl tablets with antacids can cause the enteric coating of the bisacody tablet to dissolve prematurely, leading to possible gastric irritation or dyspepsia. Avoid antacids within 1 hour before or after the bisacodyl dosage.

Bismuth Subcitrate Potassium; Metronidazole; Tetracycline: (Moderate) Separate administration of tetracycline and antacids by 2 to 3 hours. Coadministration may impair absorption of tetracycline which may decrease its efficacy.

Bismuth Subsalicylate; Metronidazole; Tetracycline: (Moderate) Separate administration of tetracycline and antacids by 2 to 3 hours. Coadministration may impair absorption of tetracycline which may decrease its efficacy.

Bosutinib: (Moderate) Bosutinib displays pH-dependent aqueous solubility; therefore, concomitant use of bosutinib and antacids may result in decreased plasma exposure of bosutinib. Separate the administration of bosutinib and antacids by more than 2 hours.

Budesonide: (Moderate) Enteric-coated budesonide granules dissolve at a pH more than 5.5. Likewise, the dissolution of the coating of extended-release budesonide tablets (Uceris) is pH dependent. Concomitant use of oral budesonide and antacids, milk, or other drugs that increase gastric pH levels can cause the coating of the granules to dissolve prematurely, possibly affecting release properties and absorption of the drug in the duodenum. In general, it may be prudent to avoid drugs such as antacids in combination with enteric-coated budesonide.

Budesonide; Formoterol: (Moderate) Enteric-coated budesonide granules dissolve at a pH more than 5.5. Likewise, the dissolution of the coating of extended-release budesonide tablets (Uceris) is pH dependent. Concomitant use of oral budesonide and antacids, milk, or other drugs that increase gastric pH levels can cause the coating of the granules to dissolve prematurely, possibly affecting release properties and absorption of the drug in the duodenum. In general, it may be prudent to avoid drugs such as antacids in combination with enteric-coated budesonide.

Budesonide; Glycopyrrolate; Formoterol: (Moderate) Enteric-coated budesonide granules dissolve at a pH more than 5.5. Likewise, the dissolution of the coating of extended-release budesonide tablets (Uceris) is pH dependent. Concomitant use of oral budesonide and antacids, milk, or other drugs that increase gastric pH levels can cause the coating of the granules to dissolve prematurely, possibly affecting release properties and absorption of the drug in the duodenum. In general, it may be prudent to avoid drugs such as antacids in combination with enteric-coated budesonide.

Bumetanide: (Moderate) Monitor potassium concentration before and during concomitant laxative, such as magnesium hydroxide, and loop diuretic use due to risk for additive hypokalemia; potassium supplementation may be necessary.

Butalbital; Acetaminophen: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Butalbital; Acetaminophen; Caffeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Butalbital; Acetaminophen; Caffeine; Codeine: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Cabotegravir: (Moderate) Administer antacids at least two hours before or four hours after taking oral cabotegravir. The chemical structure of these antacids contains aluminum or magnesium which can bind cabotegravir in the GI tract. Taking these drugs simultaneously may result in reduced oral bioavailability of cabotegravir.

Cabotegravir; Rilpivirine: (Moderate) Administer antacids at least two hours before or four hours after taking oral cabotegravir. The chemical structure of these antacids contains aluminum or magnesium which can bind cabotegravir in the GI tract. Taking these drugs simultaneously may result in reduced oral bioavailability of cabotegravir. (Moderate) Concurrent administration of rilpivirine and antacids may significantly decrease rilpivirine plasma concentrations, potentially resulting in treatment failure. To decrease the risk of virologic failure, avoid use of antacids for at least 2 hours before and at least 4 hours after administering rilpivirine.

Calcium Carbonate; Risedronate: (Moderate) Magnesium hydroxide will interfere with the absorption of risedronate. Do not take magnesium hydroxide within 2 hours of taking risedronate.

Capecitabine: (Minor) Monitor for an increase in capecitabine-related adverse reactions if coadministration with magnesium hydroxide is necessary. When a magnesium hydroxide-containing antacid was administered immediately after capecitabine, the AUC and Cmax of capecitabine increased by 16% and 35%, respectively; the AUC and Cmax of metabolite 5'-DFCR increased by 18% and 22%, respectively. No effect was observed on the other three major metabolites of capecitabine (5'-DFUR, fluorouracil, FBAL).

Captopril: (Major) Antacids can decrease the GI absorption of captopril if administered simultaneously.

Captopril; Hydrochlorothiazide, HCTZ: (Major) Antacids can decrease the GI absorption of captopril if administered simultaneously.

Carbonic anhydrase inhibitors: (Moderate) Diuretics may interfere with the kidneys ability to regulate magnesium concentrations. Long-term use of diuretics may impair the magnesium-conserving ability of the kidneys and lead to hypomagnesemia.

Cefdinir: (Moderate) Antacids containing magnesium or aluminum can interfere with the absorption of cefdinir. If aluminum or magnesium containing antacids are required during cefdinir therapy, cefdinir should be taken at least 2 hours before or after the antacid.

Cefditoren: (Major) Separate the administration of cefditoren and magnesium- or aluminum-containing antacids by at least 2 hours. Coadministration interferes with cefditoren absorption causing a decrease in the Cmax and AUC. Other orally administered aluminum or magnesium salts may also interfere with cefditoren absorption.

Cefpodoxime: (Moderate) Cefpodoxime proxetil requires a low gastric pH for dissolution; therefore, concurrent administration with medications that increase gastric pH (e.g., antacids) may decrease the bioavailability of cefpodoxime. Concomitant administration with high doses of antacids reduces peak plasma concentrations by 24% and the extent of absorption by 27%. The rate of absorption is not affected.

Cefuroxime: (Moderate) Antacids can interfere with the oral absorption of cefuroxime axetil and may result in reduced antibiotic efficacy. If an antacid must be used while a patient is taking cefuroxime, administer the oral dosage of cefuroxime at least 1 hour before or 2 hours after the antacid.

Chloroquine: (Major) Chloroquine absorption may be reduced by antacids. Administer chloroquine and antacids at least 4 hours apart.

Chlorpheniramine; Hydrocodone: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Chlorpromazine: (Moderate) The absorption of chlorpromazine liquids, suspensions, or concentrates may be decreased by co-administration of antacids. It may be advisable to separate chlorpromazine administration from antacids by 1 to 2 hours. In a small study (n = 6), administration of a magnesium trisilicate and aluminum hydroxide liquid gel antacid with a chlorpromazine liquid suspension resulted in a statistically significant decrease in chlorpromazine concentrations (average 20% decline; approximate range: 6% to 48%). In another kinetic study (n = 10), concurrent use of chlorpromazine liquid concentrate and an aluminum and magnesium hydroxide suspension reduced the urinary excretion of chlorpromazine by 10% to 45%. Adsorption of chlorpromazine to the antacid suspension may have contributed to a subsequent decline in urinary excretion of the drug.

Ciprofloxacin: (Moderate) Administer oral ciprofloxacin at least 2 hours before or 6 hours after magnesium hydroxide. Ciprofloxacin absorption may be reduced as quinolone antibiotics can chelate with divalent or trivalent cations.

Citric Acid; Potassium Citrate; Sodium Citrate: (Contraindicated) Avoid coadministration of antacids with citrate salts since increased absorption of aluminum can occur. In addition, some antacids like calcium carbonate, share the potential with the citrate salts for development of metabolic alkalosis, when given in higher dosage.

Conjugated Estrogens; Bazedoxifene: (Minor) In clinical evaluation, a single dose of 460 mg aluminum hydroxide and 400 mg magnesium hydroxide was given with a bazedoxifene 40 mg tablet in 30 postmenopausal women after an overnight fast. Coadministration of aluminum/magnesium hydroxide and bazedoxifene decreased Cmax of bazedoxifene by 8% and increased AUC of bazedoxifene by 7%. The clinical effect of this change is not known, but does not appear to be significant. Separating adminisration times may help limit any possible interaction.

Dasatinib: (Moderate) Separate the administration of dasatinib and antacids by at least 2 hours if these agents are used together. The simultaneous administration of an antacid with dasatinib decreased the Cmax and AUC of dasatinib by 58% and 55%, respectively.

Delafloxacin: (Major) Administer oral delafloxacin at least 2 hours before or 6 hours after products that contain magnesium hydroxide. Delafloxacin absorption may be reduced as quinolone antibiotics can chelate with divalent or trivalent cations. Examples of compounds that may interfere with quinolone bioavailability include antacids that contain magnesium hydroxide.

Delavirdine: (Major) Coadministration of delavirdine with antacids results in decreased absorption of delavirdine. Administration of delavirdine and antacids should be separated by at least 1 hour.

Demeclocycline: (Moderate) Separate administration of demeclocycline and antacids by 2 to 3 hours. Coadministration may impair absorption of demeclocycline which may decrease its efficacy.

Dextromethorphan; Quinidine: (Major) Alkalinizing agents such as antacids can increase renal tubular reabsorption of quinidine by alkalinizing the urine; higher quinidine serum concentrations and quinidine toxicity are possible.

Diazepam: (Moderate) The coadministration of diazepam with antacids results in delayed diazepam absorption due to the fact that antacids delay gastric emptying. It may be prudent to separate dosing by 2 hours to limit any potential interaction.

Dichlorphenamide: (Moderate) Use dichlorphenamide and magnesium hydroxide together with caution. Dichlorphenamide increases potassium excretion and can cause hypokalemia and should be used cautiously with other drugs that may cause hypokalemia including laxatives. Measure potassium concentrations at baseline and periodically during dichlorphenamide treatment. If hypokalemia occurs or persists, consider reducing the dichlorphenamide dose or discontinuing dichlorphenamide therapy.

Diclofenac; Misoprostol: (Major) Avoid concomitant use of magnesium-containing antacids, such as magnesium hydroxide, and misoprostol in order to minimize misoprostol-associated diarrhea.

Didanosine, ddI: (Minor) The side effects associated with magnesium hydroxide may potentially be increased during concurrent use with didanosine, ddI because some ddI products also contain similar antacid ingredients. Although this interaction should be of minor clinical significance for most patients, clinicians should be alert to a possible increased risk of side effects associated with taking an additional antacid product concurrently with ddI products.

Diflunisal: (Moderate) Concurrent use of diflunisal with antacids may reduce plasma diflunisal concentrations. The effect may be clinically significant if antacids are used on a continuous schedule.

Digoxin: (Moderate) Monitor digoxin concentrations as appropriate and watch for decreased digoxin efficacy if coadministration with antacids is necessary. The dose of digoxin may need to be adjusted. Antacids may decrease the absorption of digoxin.

Diphenhydramine; Naproxen: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Diphenoxylate; Atropine: (Moderate) Diphenoxylate can decrease GI motility. Drugs used to treat constipation, such as laxatives, would counteract the effect of antidiarrheals. In general, it would be illogical to concurrently administer these drugs at the same time. If an antidiarrheal medication is needed, it would be wise to temporarily discontinue use of agents with laxative effects.

Dolutegravir: (Moderate) Administer dolutegravir 2 hours before or 6 hours after taking cation-containing gastrointestinal medications such as magnesium hydroxide. The chemical structure of these GI drugs that contain polyvalent cations, such as magnesium hydroxide, can bind dolutegravir in the GI tract. Taking these drugs simultaneously may result in reduced bioavailability of dolutegravir.

Dolutegravir; Lamivudine: (Moderate) Administer dolutegravir 2 hours before or 6 hours after taking cation-containing gastrointestinal medications such as magnesium hydroxide. The chemical structure of these GI drugs that contain polyvalent cations, such as magnesium hydroxide, can bind dolutegravir in the GI tract. Taking these drugs simultaneously may result in reduced bioavailability of dolutegravir.

Dolutegravir; Rilpivirine: (Moderate) Administer dolutegravir 2 hours before or 6 hours after taking cation-containing gastrointestinal medications such as magnesium hydroxide. The chemical structure of these GI drugs that contain polyvalent cations, such as magnesium hydroxide, can bind dolutegravir in the GI tract. Taking these drugs simultaneously may result in reduced bioavailability of dolutegravir. (Moderate) Concurrent administration of rilpivirine and antacids may significantly decrease rilpivirine plasma concentrations, potentially resulting in treatment failure. To decrease the risk of virologic failure, avoid use of antacids for at least 2 hours before and at least 4 hours after administering rilpivirine.

Doxycycline: (Moderate) Separate administration of oral doxycycline and antacids by 2 to 3 hours. Coadministration may impair absorption of doxycycline which may decrease its efficacy.

Elvitegravir; Cobicistat; Emtricitabine; Tenofovir Alafenamide: (Moderate) Separate administration of elvitegravir and antacids by at least 2 hours. Due to the formation of ionic complexes in the gastrointestinal tract, simultaneous administration results in lower elvitegravir plasma concentrations.

Elvitegravir; Cobicistat; Emtricitabine; Tenofovir Disoproxil Fumarate: (Moderate) Separate administration of elvitegravir and antacids by at least 2 hours. Due to the formation of ionic complexes in the gastrointestinal tract, simultaneous administration results in lower elvitegravir plasma concentrations.

Emtricitabine; Rilpivirine; Tenofovir alafenamide: (Moderate) Concurrent administration of rilpivirine and antacids may significantly decrease rilpivirine plasma concentrations, potentially resulting in treatment failure. To decrease the risk of virologic failure, avoid use of antacids for at least 2 hours before and at least 4 hours after administering rilpivirine.

Emtricitabine; Rilpivirine; Tenofovir Disoproxil Fumarate: (Moderate) Concurrent administration of rilpivirine and antacids may significantly decrease rilpivirine plasma concentrations, potentially resulting in treatment failure. To decrease the risk of virologic failure, avoid use of antacids for at least 2 hours before and at least 4 hours after administering rilpivirine.

Erlotinib: (Major) Separate administration by several hours if concomitant use of erlotinib and antacids is necessary. Erlotinib displays pH-dependent solubility with decreased solubility at a higher pH; the increased gastric pH resulting from antacid therapy may reduce the bioavailability of erlotinib. Increasing the dose of erlotinib without modifying the administration schedule is unlikely to compensate for loss of exposure. The effects of antacids on erlotinib pharmacokinetics has not been evaluated.

Ethacrynic Acid: (Moderate) Monitor potassium concentration before and during concomitant laxative, such as magnesium hydroxide, and loop diuretic use due to risk for additive hypokalemia; potassium supplementation may be necessary.

Ethotoin: (Major) Magnesium hydroxide inhibits the absorption of ethotoin. Simultaneous administration should be avoided; separate dosing by at least 2 hours to limit an interaction.

Ezetimibe: (Minor) Antacids may decrease the peak plasma concentration (Cmax) of total ezetimibe by 30%. The effect of the antacids in this regard is not expected to have a significant effect on the ability of ezetimibe to lower cholesterol. However, to limit any potential interaction, it would be prudent to administer ezetimibe at least 1 hour before or 2 hours after administering antacids.

Ezetimibe; Simvastatin: (Minor) Antacids may decrease the peak plasma concentration (Cmax) of total ezetimibe by 30%. The effect of the antacids in this regard is not expected to have a significant effect on the ability of ezetimibe to lower cholesterol. However, to limit any potential interaction, it would be prudent to administer ezetimibe at least 1 hour before or 2 hours after administering antacids.

Ferric Maltol: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Fexofenadine: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.

Fexofenadine; Pseudoephedrine: (Moderate) Coadministration with antacids (containing aluminum or magnesium) within 15 minutes decreases the AUC and Cmax of fexofenadine by 41% and 43%, respectively. Separate administration is recommended.

Fosamprenavir: (Moderate) Administer fosamprenavir at least 1 hour before or 1 hour after antacids. Coadministration may decrease the exposure of fosamprenavir and impair its efficacy.

Fosinopril: (Moderate) Coadministration of antacids with fosinopril may impair absorption of fosinopril. Therefore, if concomitant administration of these agents is indicated, dosing should be separated by 2 hours.

Fosinopril; Hydrochlorothiazide, HCTZ: (Moderate) Coadministration of antacids with fosinopril may impair absorption of fosinopril. Therefore, if concomitant administration of these agents is indicated, dosing should be separated by 2 hours.

Furosemide: (Moderate) Monitor potassium concentration before and during concomitant laxative, such as magnesium hydroxide, and loop diuretic use due to risk for additive hypokalemia; potassium supplementation may be necessary.

Gabapentin: (Moderate) Gabapentin should be taken at least 2 hours after the administration of antacids. Antacids have been shown to reduce the oral bioavailability of gabapentin by roughly 20%. This decrease in bioavailability was about 5% when gabapentin was administered 2 hours after the antacid.

Gastrointestinal Enzymes: (Major) The effectiveness of gastrointestinal enzymes can be diminished with concurrent administration of antacids. In-vitro studies suggest that calcium and magnesum cations exert their deleterious effect on replacement enzyme therapy by formation of poorly soluble calcium or magnesium soaps and precipitation of glycine conjugated bile salts.

Gefitinib: (Major) Avoid coadministration of antacids with gefitinib if possible due to decreased exposure to gefitinib, which may lead to reduced efficacy. If concomitant use is unavoidable, take gefitinib 6 hours after the last dose or 6 hours before the next antacid dose. Gefitinib exposure is affected by gastric pH. Coadministration with another drug to maintain gastric pH above 5 decreased gefitinib exposure by 47%.

Gemifloxacin: (Major) Administer magnesium hydroxide at least 3 hours before or 2 hours after gemifloxacin. Gemifloxacin absorption may be reduced as quinolone antibiotics can chelate with divalent or trivalent cations. Examples of compounds that may interfere with quinolone bioavailability include antacids that contain magnesium hydroxide.

Glipizide: (Moderate) Antacids have been reported to increase the absorption of glipizide, enhancing its hypoglycemic effects. Although the exact mechanism is not known, theoretically it may be due to alterations in gastric pH. If these drugs must be used together, give glipizide at least 2 hours prior to the antacid. Consider closely monitoring blood glucose concentrations.

Glipizide; Metformin: (Moderate) Antacids have been reported to increase the absorption of glipizide, enhancing its hypoglycemic effects. Although the exact mechanism is not known, theoretically it may be due to alterations in gastric pH. If these drugs must be used together, give glipizide at least 2 hours prior to the antacid. Consider closely monitoring blood glucose concentrations.

Glyburide: (Moderate) Antacids have been reported to increase the absorption of non-micronized glyburide, enhancing their hypoglycemic effects. Although the exact mechanism is not known, theoretically it may be due to alterations in gastric pH. If antacids must be used while a patient is taking glyburide, give the glyburide at least 2 hours prior to the antacid. Consider closely monitoring blood glucose concentrations.

Glyburide; Metformin: (Moderate) Antacids have been reported to increase the absorption of non-micronized glyburide, enhancing their hypoglycemic effects. Although the exact mechanism is not known, theoretically it may be due to alterations in gastric pH. If antacids must be used while a patient is taking glyburide, give the glyburide at least 2 hours prior to the antacid. Consider closely monitoring blood glucose concentrations.

Guaifenesin; Hydrocodone: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Guaifenesin; Hydrocodone; Pseudoephedrine: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Homatropine; Hydrocodone: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Hydrocodone: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Hydrocodone; Ibuprofen: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Hydrocodone; Pseudoephedrine: (Minor) Concurrent use of hydrocodone with strong laxatives that rapidly increase gastrointestinal motility, such as magnesium hydroxide, may decrease hydrocodone absorption. Closely monitor patients for changing analgesic requirements or adverse events.

Hydroxychloroquine: (Moderate) Hydroxychloroquine absorption may be reduced by antacids as has been observed with the structurally similar chloroquine. Administer hydroxychloroquine and antacids at least 4 hours apart. Of note, a study demonstrated no significant difference in hydroxychloroquine serum concentration in patients taking concomitant antacids (n = 14) compared to those not taking antacids (n = 495).

Hyoscyamine; Methenamine; Methylene Blue; Phenyl Salicylate; Sodium Biphosphate: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Indomethacin: (Moderate) Antacids may inhibit the oral absorption of indomethacin. Simultaneous administration should be avoided; separate dosing by at least 2 hours to limit an interaction.

Infigratinib: (Moderate) Separate the administration of infigratinib and locally acting antacids if concomitant use is necessary. Coadministration may decrease infigratinib exposure resulting in decreased efficacy. Administer infigratinib two hours before or after an antacid.

Iron Salts: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Iron: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Isoniazid, INH; Pyrazinamide, PZA; Rifampin: (Moderate) Concomitant use of antacids and rifampin may decrease the absorption of rifampin. Daily doses of rifampin should be given at least 1 hour before the ingestion of antacids.

Isoniazid, INH; Rifampin: (Moderate) Concomitant use of antacids and rifampin may decrease the absorption of rifampin. Daily doses of rifampin should be given at least 1 hour before the ingestion of antacids.

Itraconazole: (Moderate) When administering antacids with the 100 mg itraconazole capsule and 200 mg itraconazole tablet formulations, systemic exposure to itraconazole is decreased. Conversely, exposure to itraconazole is increased when antacids are administered with the 65 mg itraconazole capsule. Administer antacids at least 2 hours before or 2 hours after the 100 mg capsule or 200 mg tablet. Monitor for increased itraconazole-related adverse effects if antacids are administered with itraconazole 65 mg capsules.

Ketoconazole: (Moderate) Administer antacids at least 1 hour before or 2 hours after taking ketoconazole. Antacids can impair the absorption of ketoconazole.

Lactulose: (Major) In general, other laxatives should not be used concurrently with lactulose, especially during the initial phase of therapy for portal-systemic encephalopathy, because the loose stools resulting from their use may falsely suggest that adequate lactulose dosage has been achieved. Studies suggest that oral, nonabsorbable antacids and/or laxatives like magnesium hydroxide can interfere with the decrease in colon pH necessary for lactulose's action and these alterations may make it challenging to titrate an accurate dose of lactulose during treatment of hepatic encephalopathy.

Lansoprazole; Naproxen: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Ledipasvir; Sofosbuvir: (Moderate) Separate administration of ledipasvir and antacids by at least 4 hours. Solubility of ledipasvir decreases as gastric pH increases; thus, simultaneous administration of these drugs may result in lower ledipasvir plasma concentrations.

Levofloxacin: (Moderate) Administer magnesium hydroxide at least 2 hours before or 2 hours after orally administered levofloxacin. Levofloxacin absorption may be reduced as quinolone

antibiotics can chelate with divalent or trivalent cations. Chelation of divalent cations with levofloxacin is less than with other quinolones.

Levoketoconazole: (Moderate) Administer antacids at least 1 hour before or 2 hours after taking ketoconazole. Antacids can impair the absorption of ketoconazole.

Loop diuretics: (Moderate) Monitor potassium concentration before and during concomitant laxative, such as magnesium hydroxide, and loop diuretic use due to risk for additive hypokalemia; potassium supplementation may be necessary.

Mefenamic Acid: (Moderate) Ingestion of mefenamic acid with antacids is not recommended. Administration with an antacid containing 1.7 grams of magnesium hydroxide resulted in a 36 percent increase in the area under the time versus concentration curve of mefenamic acid.

Mefloquine: (Moderate) Antacids, H2-blockers, and proton pump inhibitors (PPIs) may increase plasma concentrations of mefloquine. In a small study involving 6 healthy subjects and 6 peptic ulcer patients, cimetidine increased the Cmax and AUC of mefloquine. In the study, the pharmacokinetics of mefloquine were determined after receiving a single oral mefloquine 500 mg dose alone and after 3-days of cimetidine 400 mg PO bid. In both healthy subjects and peptic ulcer patients, Cmax was increased 42.4% and 20.5%, respectively. The AUC was increased by 37.5% in both groups. Elimination half-life, total clearance, and volume of distribution were not significantly affected. An increase in adverse reactions was not noted. Patients on chronic mefloquine therapy might be at increased risk of adverse reactions, especially in patients with a neurological or psychiatric history.

Mesalamine, 5-ASA: (Moderate) Do not coadminister mesalamine extended-release capsules (Apriso) with antacids. Apriso is a pH-dependent, delayed-release capsule product with an enteric coating that dissolves at a pH of at least 6. Other mesalamine products do not have an interaction with antacids.

Methenamine: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Methenamine; Sodium Acid Phosphate: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Methenamine; Sodium Acid Phosphate; Methylene Blue; Hyoscyamine: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased

urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Methenamine; Sodium Salicylate: (Major) The therapeutic action of methenamine requires an acidic urine. Antacids containing alkalinizing agents such as sodium bicarbonate can alkalinize the urine, thereby decreasing the effectiveness of methenamine by increasing the amount of non-ionized drug available for renal tubular reabsorption. Increased urine alkalinity also can inhibit the conversion of methenamine to formaldehyde, which is the active bacteriostatic form; concurrent use of methenamine and urinary alkalizers is not recommended.

Minocycline: (Moderate) Separate administration of minocycline and antacids by 2 to 3 hours. Coadministration may impair absorption of minocycline which may decrease its efficacy.

Misoprostol: (Major) Avoid concomitant use of magnesium-containing antacids, such as magnesium hydroxide, and misoprostol in order to minimize misoprostol-associated diarrhea.

Moxifloxacin: (Major) Administer oral moxifloxacin at least 4 hours before or 8 hours after magnesium hydroxide. Moxifloxacin absorption may be reduced as quinolone antibiotics can chelate with divalent or trivalent cations. Examples of compounds that may interfere with quinolone bioavailability include antacids that contain magnesium hydroxide.

Mycophenolate: (Major) Coadministration of mycophenolate mofetil with antacids decreases the bioavailability of mycophenolate mofetil. Aluminum/magnesium hydroxide antacids decrease the AUC of mycophenolic acid by about 17% when given as mycophenolate mofetil. Decreased absorption of mycophenolate (possible chelation) is the likely etiology for reduced systemic exposure. If antacids and mycophenolate need to be used together, separate administration times are recommended (do not give simultaneously).

Naproxen: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Naproxen; Esomeprazole: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Naproxen; Pseudoephedrine: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Neratinib: (Major) Administer neratinib at least 3 hours after administration of antacids if concomitant use is necessary due to decreased absorption and systemic exposure of neratinib; the solubility of neratinib decreases with increasing pH of the GI tract. The efficacy of neratinib may be decreased.

Nilotinib: (Moderate) If concomitant use of these agents is necessary, administer the antacid approximately 2 hours before or approximately 2 hours after the nilotinib dose. Nilotinib displays pH-dependent solubility with decreased solubility at a higher pH; therefore, concomitant use of nilotinib and antacids may result in decreased bioavailability of nilotinib. In a study in healthy subjects, there was no significant change in nilotinib pharmacokinetics when an antacid (aluminum hydroxide/magnesium hydroxide/simethicone) was administered approximately 2 hours before or approximately 2 hours after a single 400-mg nilotinib dose.

Norethindrone Acetate; Ethinyl Estradiol; Ferrous fumarate: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Norethindrone; Ethinyl Estradiol; Ferrous fumarate: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Octreotide: (Moderate) Coadministration of oral octreotide with antacids may require increased doses of octreotide. Coadministration of oral octreotide with drugs that alter the pH of the upper GI tract, including antacids, may alter the absorption of octreotide and lead to a reduction in bioavailability.

Ofloxacin: (Moderate) Administer magnesium hydroxide at least 2 hours before or 2 hours after ofloxacin. Ofloxacin absorption may be reduced as quinolone antibiotics can chelate with divalent or trivalent cations. Examples of compounds that may interfere with quinolone bioavailability include antacids that contain magnesium hydroxide.

Omadacycline: (Moderate) Separate administration of omadacycline and antacids by 4 hours. Coadministration may impair absorption of omadacycline which may decrease its efficacy.

Pancrelipase: (Major) The effectiveness of gastrointestinal enzymes can be diminished with concurrent administration of antacids. In-vitro studies suggest that calcium and magnesum cations exert their deleterious effect on replacement enzyme therapy by formation of poorly soluble calcium or magnesium soaps and precipitation of glycine conjugated bile salts.

Pazopanib: (Moderate) Separate administration of pazopanib and antacids by several hours if coadministration is necessary in order to avoid a reduction in pazopanib exposure, which may decrease efficacy.

Penicillamine: (Moderate) Because penicillamine chelates heavy metals, it is possible that antacids could reduce penicillamine bioavailability, which can decrease the therapeutic effects of penicillamine. Simultaneous administration should be avoided; separate dosing by at least 2 hours to limit an interaction.

Pexidartinib: (Moderate) Administer pexidartinib 2 hours before or after locally-acting antacids as concurrent administration may reduce pexidartinib exposure. Although the effects of locally-

acting antacids on pexidartinib pharmacokinetics have not been studied, other acid-reducing agents have been shown to decrease pexidartinib exposure by 50%.

Phenytoin: (Moderate) Because the absorption of phenytoin suspension can be reduced by antacids containing magnesium, aluminum, or calcium, administration at the same time of day should be avoided when possible. Ingestion times of phenytoin capsules and calcium antacids should be staggered in patients with low serum phenytoin levels to prevent absorption difficulties. Studies evaluating the effects of magnesium-aluminium antacids on the absorption of phenytoin capsules or tablets have yielded conflicting results. Nevertheless, serum phenytoin levels and clinical response should be closely monitored if these agents are co-administered. The mechanisms by which antacids reduce phenytoin absorption may involve increased gastric transit time, chelation, adsorption, and/or altered solubility. The oral absorption of phenytoin may be reduced by calcium carbonate (e.g., as found in antacids) or other calcium salts. Calcium products may form complexes with phenytoin that are nonabsorbable. Although the magnitude of the interaction is not great, an occasional patient may be affected and the interaction may lead to subtherapeutic phenytoin concentrations. Separating the administration of phenytoin and antacids or calcium salts by at least 2 hours will help minimize the possibility of interaction.

Phosphorus: (Moderate) Phosphate may bind magnesium salts and magnesium-containing antacids (e.g., magnesium carbonate, magnesium hydroxide) may limit phosphorus absorption or phosphorus may limit magnesium absorption. If the patient requires magnesium supplements or a magnesium-containing antacid, it may be wise to separate the administration of phosphates from magnesium-containing products.

Polyethylene Glycol; Electrolytes; Bisacodyl: (Minor) The concomitant use of bisacodyl tablets with antacids can cause the enteric coating of the bisacody tablet to dissolve prematurely, leading to possible gastric irritation or dyspepsia. Avoid antacids within 1 hour before or after the bisacodyl dosage.

Polysaccharide-Iron Complex: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Potassium Citrate: (Contraindicated) Avoid coadministration of antacids with citrate salts since increased absorption of aluminum can occur. In addition, some antacids like calcium carbonate, share the potential with the citrate salts for development of metabolic alkalosis, when given in higher dosage.

Propranolol: (Moderate) Antacids may reduce the absorption of propranolol. The need to stagger doses of propranolol has not been established, but may be prudent. Monitor clinical response, and adjust propranolol dosage if needed to attain therapeutic goals.

Propranolol; Hydrochlorothiazide, HCTZ: (Moderate) Antacids may reduce the absorption of propranolol. The need to stagger doses of propranolol has not been established, but may be prudent. Monitor clinical response, and adjust propranolol dosage if needed to attain therapeutic goals.

Quinidine: (Major) Alkalinizing agents such as antacids can increase renal tubular reabsorption of quinidine by alkalinizing the urine; higher quinidine serum concentrations and quinidine toxicity are possible.

Quinine: (Major) Antacids may delay or decrease the absorption of quinine.

Raltegravir: (Major) Coadministration or staggered administration of aluminum and/or magnesium-containing antacids is not recommended during treatment with raltegravir. Coadministration may result in decreased plasma concentrations of raltegravir, which may lead to HIV treatment failure or the development of viral resistance. In a drug interaction study, the AUC for raltegravir was decreased by 49% (90% CI, 35% to 60%), 51% (90% CI, 33% to 65%), and 30% (90% CI, 4% to 50%), when administered with, 2 hours before, and 2 hours after aluminum/magnesium hydroxide antacids, respectively.

Rifampin: (Moderate) Concomitant use of antacids and rifampin may decrease the absorption of rifampin. Daily doses of rifampin should be given at least 1 hour before the ingestion of antacids.

Rilpivirine: (Moderate) Concurrent administration of rilpivirine and antacids may significantly decrease rilpivirine plasma concentrations, potentially resulting in treatment failure. To decrease the risk of virologic failure, avoid use of antacids for at least 2 hours before and at least 4 hours after administering rilpivirine.

Riociguat: (Major) Separate administration of riociguat from antacids by at least 1 hour. Antacids such as aluminum hydroxide/magnesium hydroxide decrease riociguat absorption.

Risedronate: (Moderate) Magnesium hydroxide will interfere with the absorption of risedronate. Do not take magnesium hydroxide within 2 hours of taking risedronate.

Rosuvastatin: (Moderate) Coadministration of rosuvastatin with antacids has reduced rosuvastatin plasma concentrations by 54%. When the antacid is given 2 hours after rosuvastatin, no significant change in rosuvastatin plasma concentrations is observed.

Rosuvastatin; Ezetimibe: (Moderate) Coadministration of rosuvastatin with antacids has reduced rosuvastatin plasma concentrations by 54%. When the antacid is given 2 hours after rosuvastatin, no significant change in rosuvastatin plasma concentrations is observed. (Minor) Antacids may decrease the peak plasma concentration (Cmax) of total ezetimibe by 30%. The effect of the antacids in this regard is not expected to have a significant effect on the ability of ezetimibe to lower cholesterol. However, to limit any potential interaction, it would be prudent to administer ezetimibe at least 1 hour before or 2 hours after administering antacids.

Sarecycline: (Major) Separate administration of sarecycline and antacids by 2 to 3 hours. Coadministration may impair absorption of sarecycline which may decrease its efficacy.

Selpercatinib: (Major) Avoid coadministration of selpercatinib with antacids due to the risk of decreased selpercatinib exposure which may reduce its efficacy. If concomitant use is unavoidable, take selpercatinib 2 hours before or 2 hours after administration of antacids. Coadministration with acid-reducing agents decreases selpercatinib plasma concentrations.

Sodium Citrate; Citric Acid: (Contraindicated) Avoid coadministration of antacids with citrate salts since increased absorption of aluminum can occur. In addition, some antacids like calcium carbonate, share the potential with the citrate salts for development of metabolic alkalosis, when given in higher dosage.

Sodium Ferric Gluconate Complex; ferric pyrophosphate citrate: (Moderate) Doses of antacids and iron should be taken as far apart as possible to minimize the potential for interaction. Antacids may decrease the absorption of oral iron preparations. At higher pH values, iron is more readily ionized to its ferric state and is more poorly absorbed.

Sodium Polystyrene Sulfonate: (Major) Simultaneous oral administration of cation-donating antacids or laxatives may reduce the potassium exchange capability of sodium polystyrene sulfonate. Examples of cation-donating antacids and laxatives include aluminum hydroxide, calcium carbonate, magnesium carbonate, magnesium citrate, and magnesium hydroxide. Patients who received concomitant oral sodium polystyrene sulfonate and non-absorbable cation-donating antacids and laxatives have developed systemic alkalosis. Intestinal obstruction due to concretions of aluminum hydroxide when used in combination with sodium polystyrene sulfonate has also been reported. One case of grand mal seizure has been reported in a patient with chronic hypocalcemia of renal failure who was given sodium polystyrene with magnesium hydroxide as laxative. Normally, antacids like magnesium hydroxide and calcium carbonate neutralize hydrochloric acid in the stomach, forming magnesium chloride and calcium chloride. As these compounds enter the small intestine, they react with bicarbonate, forming magnesium carbonate and calcium carbonate, which are insoluble. If polystyrene is administered, it blocks this reaction by binding to the magnesium and calcium ions before they can react with the bicarbonate. More hydrogen ions are lost from the stomach than are lost from the intestine, resulting in metabolic alkalosis. Rectal administration of sodium polystyrene sulfonate may reduce the severity of these interactions.

Sofosbuvir; Velpatasvir: (Moderate) Separate the use of antacids and velpatasvir administration by 4 hours. Velpatasvir solubility decreases as pH increases; therefore, drugs that increase gastric pH are expected to decrease the concentrations of velpatasvir, potentially resulting in loss of antiviral efficacy.

Sofosbuvir; Velpatasvir; Voxilaprevir: (Moderate) Separate the use of antacids and velpatasvir administration by 4 hours. Velpatasvir solubility decreases as pH increases; therefore, drugs that increase gastric pH are expected to decrease the concentrations of velpatasvir, potentially resulting in loss of antiviral efficacy.

Sotalol: (Moderate) Coadministration of antacids with sotalol reduces the Cmax and AUC of sotalol by 26% and 20%, respectively. This interaction results in a 25% reduction in the bradycardic effect of sotalol (measured at rest). Antacid administration two hours after the sotalol dose does not alter sotalol pharmacokinetics or pharmacodynamics. Instruct patients to avoid using antacids containing aluminum hydroxide or magnesium hydroxide within 2 hours of taking sotalol.

Sotorasib: (Moderate) Avoid coadministration of sotorasib and gastric-reducing agents, such as antacids. Coadministration may decrease sotorasib exposure resulting in decreased efficacy. If

coadministration with antacids is necessary, administer sotorasib 4 hours before or 10 hours after an antacid.

Sparsentan: (Moderate) Administer sparsentan 2 hours before or after antacids. Simultaneous coadministration may decrease sparsentan exposure and efficacy. Medications that affect gastric pH may reduce sparsentan absorption.

Sucralfate: (Moderate) Antacids can interfere with the binding capacity of sucralfate to the GI mucosa, decreasing its effectiveness. Antacids should not be administered within 30 minutes of sucralfate. In addition, antacids or other aluminum-containing agents should be used cautiously with sucralfate in patients with chronic renal failure due to the aluminum content of sucralfate and the potential for aluminum toxicity.

Sumatriptan; Naproxen: (Minor) Concomitant administration of antacids can delay the absorption of naproxen. Periodic antacid use should not be problematic as long as the antacid and enteric-coated naproxen administration are separated by at least 2 hours.

Tacrolimus: (Major) Monitor tacrolimus whole blood trough concentration and reduce tacrolimus dose if needed during concurrent use of antacids. Magnesium and aluminum hydroxide antacids may increase the blood concentration of tacrolimus. In a single-dose crossover study in healthy volunteers, coadministration of tacrolimus and magnesium-aluminum-hydroxide resulted in a mean AUC increase of 21% and a 10% decrease in the mean tacrolimus Cmax, compared to tacrolimus administration alone.

Tetracycline: (Moderate) Separate administration of tetracycline and antacids by 2 to 3 hours. Coadministration may impair absorption of tetracycline which may decrease its efficacy.

Ticlopidine: (Major) Administration of ticlopidine after antacids resulted in an 18% decrease in plasma levels of ticlopidine. Staggering the times of administration may avoid this pharmacokinetic interaction.

Tipranavir: (Moderate) Concurrent administration of tipranavir and ritonavir with antacids results in decreased tipranavir concentrations. Administer tipranavir and ritonavir 2 hours before or 1 hour after antacids.

Torsemide: (Moderate) Monitor potassium concentration before and during concomitant laxative, such as magnesium hydroxide, and loop diuretic use due to risk for additive hypokalemia; potassium supplementation may be necessary.

Tramadol; Acetaminophen: (Minor) Antacids can delay the oral absorption of acetaminophen, but the interactions are not likely to be clinically significant as the extent of acetaminophen absorption is not appreciably affected.

Trospium: (Moderate) Antacids may inhibit the oral absorption of antimuscarinics. Simultaneous oral administration should be avoided when feasible; separate dosing by at least 2 hours to limit an interaction.

Valproic Acid, Divalproex Sodium: (Minor) Antacids containing magnesium and aluminum hydroxide have been shown to increase valproic acid AUC by an average of 12%. Although this finding is of marginal clinical significance, patients should be monitored for adverse effects in this situation.

Vitamin D analogs: (Major) Avoid vitamin D analog coadministration with magnesium hydroxide in persons on chronic hemodialysis due to the risk for hypermagnesemia.

Vitamin D: (Major) Avoid vitamin D coadministration with magnesium hydroxide in persons on chronic hemodialysis due to the risk for hypermagnesemia.

4.6. Pregnancy and Lactation

When used occasionally at recommended doses, magnesium hydroxide laxatives and antacids appear to be safe and effective to use during pregnancy, provided the pregnant individual does not have concerns with renal dysfunction. The safest first-line occasional constipation treatments to use during pregnancy are those that are not absorbed systemically (e.g., fiber, bulk-forming laxatives, stool softeners). Osmotic laxatives like magnesium hydroxide may also be used for occasional constipation when needed. Psyllium, docusate sodium or polyethylene glycol 3350 have minimal systemic absorption and can be considered for chronic constipation. Guidelines recommend a trial of lifestyle modifications as first-line therapy for heartburn and gastroesophageal reflux disease (GERD), followed by antacids such as magnesium hydroxide-containing antacid products. For ongoing symptoms, histamine type 2-receptor antagonists (H2RAs) can be used to control heartburn symptoms in pregnancy. Proton pump inhibitors should be reserved for patients who fail H2RA therapy.

When chronic high doses are avoided, magnesium hydroxide laxatives and antacids appear to be safe and effective to use during breast-feeding. With maternal magnesium supplementation, no significant changes in breast milk magnesium concentrations appear to occur; the concentration of magnesium in breast milk is not influenced by maternal magnesium intake. No problems with magnesium hydroxide use have been reported in the breastfed infant; this antacid/laxative does not concentrate in breast milk.

4.7. Effects of ability to drive and use machines

Milk of Magnesia has no effect on a person’s ability to drive or use heavy machines as long as the recommended dose if followed and no contraindications are present.

4.8. Undesirable effects

Milk of Magnesia may cause the following side-effects.

- Diarrhea
- Stomach cramps
- Nausea
- Vomiting
- Skin flushing
- drowsiness

4.9. Overdose

Seek medical attention in the case of accidental exposure or overdose (exceeding the maximum daily dose)

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: laxative

ATC Code: A06AD02

Mechanism of Action: Magnesium hydroxide (milk of magnesia) is a saline laxative that rapidly reacts with gastric acid to form water and magnesium chloride, which neutralizes gastric acid. The wall of the small intestine acts as a semipermeable membrane to magnesium and retains the highly osmotic ion in the intestine. The presence of the magnesium ion draws water into the intestine, causing an increase in intraluminal pressure. This increased pressure exerts a mechanical stimulus that increases intestinal motility. There is also evidence that magnesium, and other saline laxatives, stimulate the release of the hormone cholecystokinin-pancreozymin, which favors accumulation of fluid and electrolytes within the intestinal lumen.

Magnesium hydroxide is administered orally. In the stomach magnesium hydroxide reacts with hydrochloric acid to form magnesium chloride. Approximately 15-30% of the magnesium chloride is absorbed and rapidly excreted by the kidneys in patients with normal renal function. Any magnesium hydroxide that is not converted to magnesium chloride is subsequently changed in the small intestine to soluble but poorly absorbed salts. The magnesium that is not absorbed remains in the GI tract and is excreted in the feces.

5.2. Pharmacokinetic properties

Route-Specific Pharmacokinetics:

Oral Route

The onset of laxative action of magnesium hydroxide ranges between 30 minutes and 8 hours.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity, local tolerance, genotoxicity, and carcinogenic potential. Reproductive toxicity studies in animals were insufficient to rule out a teratogenic effect of Milk of Magnesia in humans.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified Water

Sodium hypochlorite

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

Indicated on Bottle and Label

6.4. Special precautions for storage

Store at room temperature and avoid freezing.

Do not use if imprinted neckband is missing or broken

6.5. Nature and contents of container <and special equipment for use, administration, or implantation>

355 mL bottle

6.6. Special precautions for disposal <and other handling

There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

7. <APPLICANT/MANUFACTURER>

Manufactured by
Geri-Care Pharmaceuticals
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Brooklyn, NY 11204