GROUP 11 GASTROINTESTINAL DRUGS

11.1 ANTACID AND ADSORBENTS

- ALUMINIUM HYDROXIDE+ MAGNESIUM HYDROXIDE
  Indication: For hyperacidity, dyspepsia, heartburn, and pain due to peptic ulcers.
  Unlabeled/investigation indication: N/A
  Usual Dose: Oral 1-2 tablespoonful 3-4 times/day 1 hour after meals.
  Adverse Reaction: Constipation, diarrhea
  Pregnancy risk factor: C
  Lactation: N/A
  Preparations: Suspensions (Aluminium hydroxide 918 mg + Magnesium hydroxide 300 mg + Simethicone 60 mg)

- ALUMINIUM HYDROXIDE+MAGNESIUM HYDROXIDE+SIMETHICONE+DICYCLOMINE
  Indication: For hyperacidity, dyspepsia, heartburn, and pain due to peptic ulcers.
  Unlabeled/investigation indication: N/A
  Usual Dose : Oral : 2-4 tablets 2 hour before or after meal.
  Pregnancy risk factor: C
  Lactation: N/A
  Preparations: Tablets (Aluminium hydroxide, Magnesium hydroxide 325 mg + Simethicone 10 mg + Dicyclomine 25 mg)

- SODIUM BICARBONATE
  Indication: Management of gastric hyperacidity
  Unlabeled/investigation indication: N/A
  Usual Dose: Oral 325 mg to 2 g 1-4 times/day.
  Pregnancy risk factor: C
  Lactation: Enters breast milk/compatible
  Preparations: Tablets 300 mg

11.2 ANTIDIARRHEA AGENTS

- LOPERAMIDE HYDROCHLORIDE
  Indication: Treatment of acute diarrhea and chronic diarrhea associated with inflammatory bowel disease.
  Unlabeled/investigation indication: Cancer treatment-induced diarrhea, chronic diarrhea caused by bowel resection.
  Usual Dose: Initial: 4 mg, followed by 2 mg after each loose stool, maximum dose 16 mg/day.
Adverse Reaction: Dizziness, constipation, abdominal cramping, nausea
Pregnancy risk factor: B
Lactation: Not recommended.
Preparations: Capsules 2 mg

11.3 ANTIFLATULENTS

- FLATULENCE

Indication: Treatment of flatulence symptomatic, mild laxative.
Unlabeled/investigation indication: N/A
Usual Dose: Oral 1-3 tablets 3 times/day after meals.
Adverse Reaction: Abdominal discomfort, electrolyte disturbances (long-term use), weight loss, urine discoloration
Pregnancy risk factor: N/A
Lactation: N/A
Preparations: Tablets NED (Cascara dried extract 65 mg, capsicum powder 8 mg, diastase 3 mg, ginger powder 48 mg, nux vomica dry extract 16 mg, asafoetida tincture 0.325 mL)

11.4 CATHARTICS AND LAXATIVE

- BISACODYL

Indication: Treatment of constipation, colonic evacuation prior to procedures or examination.
Unlabeled/investigation indication: N/A
Usual Dose: Oral 5-15 mg as single dose
Adverse Reaction: Electrolyte and fluid imbalance, mild abdominal cramps, nausea, rectal burning, vertigo, vomiting
Pregnancy risk factor: B
Lactation: N/A
Preparations: Tablets 5 mg

- LIQUID PARAFIN EMULSION

Indication: Lubricant laxative.
Unlabeled/investigation indication: N/A
Usual Dose: Oral 15-30 mL at bed time
Preparations: Emulsion 120 mL
**LACTULOSE**

**Indication:** Treatment of chronic constipation.

**Unlabeled/investigation indication:** N/A

**Usual Dose:** Constipation: Oral: 15-30 mL/day increased to 60 mL/day in 1-2 divided doses if necessary. Rectal: 200 g (300 mL) diluted with 700 mL of H₂O or NS; administer rectally via rectal balloon catheter and retain 30-60 minutes every 4-6 hours.

**Adverse Reaction:** Flatulence, diarrhea (excessive dose), abdominal discomfort, nausea, vomiting, cramping.

**Pregnancy risk factor:** B

**Lactation:** Excretion in breast milk unknown

**Preparations:** Syrup 66.7% of lactulose

---

**MAGNESIUM SULFATE+MAGNESIUM CARBONATE**

**Indication:** Saline laxative.

**Unlabeled/investigation indication:** N/A

**Usual Dose:** Oral 15 ml at bedtime.

**Pregnancy risk factor:** B

**Lactation:** N/A

**Preparations:** Mixture (Per 5 mL: magnesium sulfate 4 g, magnesium carbonate 0.6 g)

---

**UNISON**

**Indication:** Treatment of constipation

**Unlabeled/investigation indication:** N/A

**Usual Dose:** 20-40 mL

**Pregnancy risk factor:** N/A

**Lactation:** N/A

**Preparations:** Enema solution

---

**11.5 ANTIEMETICS**

**DIMENHYDRINATE**

**Indication:** Treatment and prevention of nausea, vertigo, and vomiting associated with motion sickness.

**Unlabeled/investigation indication:** Treatment of Meniere's disease.

**Usual Dose:** Oral 50-100 mg every 4-6 hours, not to exceed 400 mg/day. I.M., I.V. 50-100 mg administered 30-60 minutes prior to radiation therapy, may be repeated as needed up to a maximum of 400 mg in 24 hours.
Adverse Reaction:
- Central nervous system: Slight to moderate drowsiness, headache, fatigue, nervousness, dizziness
- Gastrointestinal: Abdominal pain, diarrhea, increased appetite, nausea, weight gain, xerostomia
- Neuromuscular & skeletal: Arthralgia
- Respiratory: Thickening of bronchial secretions, pharyngitis

Pregnancy risk factor: B

Lactation: N/A

Preparations: Tablets 50 mg, Injection 50 mg

DOMPERIDONE

Indication: For dyspepsia, digestive disorders, reflux, abdominal heaviness, heartburn, nausea, vomiting, hiccup.

Unlabeled/investigation indication: N/A

Usual Dose: GI motility disorders: Oral: 10 mg 3-4 times/day, 15-30 minutes before meals.
Nausea/vomiting associated with dopamine-agonist anti-Parkinson agents: Oral 20 mg 3-4 times/day

Adverse Reaction:
- Central nervous system: Headache/migraine
- Central nervous system: Drowsiness, fatigue, restlessness, acute dystonic, akathisia, confusion, depression, dizziness, insomnia, NMS (rare)
- Gastrointestinal: Xerostomia
- Other: abdominal cramps, extrapyramidal symptoms (rare)

Pregnancy risk factor: C

Lactation: Not recommended.

Preparations: Tablets 10 mg

METOCLOPRAMIDE

Indication: For nausea and vomiting.

Unlabeled/investigation indication: N/A

Usual Dose: Oral 10 mg 3 up to 4 times/day 30 minutes before meals or food and at bedtime. I.M., I.V. (for severe symptoms): 10 mg over 1-2 minutes.

Adverse Reaction:
- Cardiovascular: AV block, bradycardia, flushing, hyper-/hypotension, supraventricular tachycardia
- Central nervous system: Drowsiness, fatigue, restlessness, acute dystonic, akathisia, confusion, depression, dizziness, insomnia
- Dermatologic: Angioneurotic edema (rare), rash, urticaria
- Endocrine & metabolic: Amenorrhea, galactorrhea, gynecomastia, impotence
- Gastrointestinal: Diarrhea, nausea
- Genitourinary: Incontinence, urinary frequency
- Hematologic: Agranulocytosis, leukopenia, neutropenia, porphyria
- Ocular: Visual disturbance
- Respiratory: Bronchospasm, laryngeal edema (rare)

Pregnancy risk factor: B

Lactation: Not recommended.

Preparations: Tablets 10 mg ED(n), Injection 10 MG/2 ML ED(n)

11.6 AGENT FOR GI ULCERS

- RANITIDINE HYDROCHLORIDE

Indication: For the treatment of duodenal ulcer, benign gastric ulcer, postoperative ulcer, reflux esophagitis, Zollinger-Ellison syndrome.

Unlabeled/investigation indication: Recurrent postoperative ulcer, upper GI bleeding, prevention of acid-aspiration pneumonitis during surgery, and prevention of stress-induced ulcers.

Usual Dose: Duodenal ulcer: Oral treatment: 150 mg twice daily, or 300 mg once daily after the evening meal or at bedtime, maintenance 150 mg once daily at bedtime. Eradication of Helicobacter pylori: Oral 150 mg twice daily (requires combination therapy). Pathological hypersecretory conditions: Oral: 150 mg twice daily, I.V.: Continuous infusion for Zollinger-Ellison: 1 mg/kg/hour. Gastric ulcer: Oral 150 mg twice daily; maintenance: 150 mg once daily at bedtime. Erosive esophagitis: Oral: Treatment: 150 mg 4 times/day, maintenance: 150 mg twice daily. Prevention of heartburn: Oral: 75 mg 30-60 minutes before eating food, maximum dose 150 mg in 24 hours, do not use for more than 14 days, I.M.: 50 mg every 6-8 hours, I.V.: Intermittent bolus or infusion: 50 mg every 6-8 hours, Continuous I.V. infusion: 6.25 mg/hour.

Adverse Reaction:
- Cardiovascular: Arrhythmias, vasculitis
- Central nervous system: Dizziness, sedation, headache, drowsiness
- Dermatologic: Rash
- Gastrointestinal: Constipation, nausea

Pregnancy risk factor: B

Lactation: Use caution

Preparations: Tablets 150 mg ED(n), Injection 2 mL (Per mL: 20 mg) ED(n)
● OMEPRAZOLE

**Indication:** Treatment of active duodenal ulcer disease or active benign gastric ulcer, other symptoms associated with gastroesophageal reflux disease (GERD), endoscopically-diagnosed erosive esophagitis, pathological hypersecretory conditions, a multidrug regimen for *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence and maintenance healing of erosive esophagi.

**Unlabeled/investigation indication:** Healing NSAID-induced ulcers, prevention of NSAID-induced ulcers

**Usual Dose:**
- **Active duodenal ulcer:** Oral: 20 mg/day for 4-8 weeks. **Gastric ulcers:** Oral: 40 mg/day for 4-8 weeks. **GERD:** Oral: 20 mg/day for up to 4 weeks. **Erosive esophagitis:** Oral: 20 mg/day for 4-8 weeks; maintenance of healing: 20 mg/day for up to 12 months total therapy. **Peptic ulcer disease:** Eradication of *Helicobacter pylori:* Oral: 20 mg or 40 mg/day as single dose or in 2 divided doses (requires combination therapy with antibiotics). **Pathological hypersecretory conditions:** Oral: Initial: 60 mg once daily.

**Adverse Reaction:**
- Central nervous system: Headache, dizziness
- Dermatologic: Rash
- Gastrointestinal: Diarrhea, abdominal pain, nausea, vomiting, flatulence, acid regurgitation, constipation, taste perversion
- Neuromuscular & skeletal: Weakness, back pain
- Respiratory: Upper respiratory infection, cough

**Pregnancy risk factor:** C

**Lactation:** Not recommended.

**Preparations:** Capsules 20 mg (with enteric-coated granule), Powder for injection 40 mg/vial

● ESOMEPRAZOLE

**Indication:** Gastroesophageal reflux Disease (GERD). In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and healing of *Helicobacter pylori* associated duodenal ulcer.

**Unlabeled/investigation indication:** Note; Non approved in Thai FDA: Prevention of gastric ulcers in patients at risk (age 60 years and/or history of gastric ulcer) associated with continuous NSAID therapy, long-term treatment of pathological hypersecretory conditions.

**Usual Dose:**
- **Gastroesophageal reflux:** Oral: 20 mg once daily for 4 weeks. **Healing of erosive esophagitis:** Oral: Initial: 20-40 mg once daily for 4-8 weeks, maintenance: 20 mg once daily. **Peptic ulcer disease:** Eradication of *Helicobacter pylori:* Oral: 40 mg once daily for 10 days (requires combination therapy).

**Adverse Reaction:**
- Central nervous system: Headache (I.V. 11%; oral 4% to 8%)
- Gastrointestinal: Flatulence, nausea, abdominal pain, diarrhea, xerostomia, dyspepsia, constipation.
- Local: Injection site reaction
- Respiratory: Sinusitis, respiratory infection

Pregnancy risk factor: B
Lactation: Not recommended.
Preparations: Tablets 20 mg (Coated Pellet/MUPS)\textsuperscript{NED}

- RABEPRAZOLE SODIUM

Indication: Active duodenal, active benign gastric and anastomotic ulcer, erosive or ulcerative gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome Eradication of Helicobacter pylori combine with appropriate antibacterial, and other pathological hypersecretory condition.

Unlabeled/investigation indication: Maintenance of duodenal ulcer.
Adverse Reaction:
- Central nervous system: Headache
- Gastrointestinal: Diarrhea, nausea, flatulence, abdominal pain, constipation, xerostomia

Pregnancy risk factor: B
Lactation: Excretion in breast milk unknown/not recommended
Preparations: Tablets 10 mg (Film-coated)\textsuperscript{NED}

11.7 MISCELLANEOUS GI DRUGS

- METADOXINE

Indication: Alcoholic fatty liver.

Unlabeled/investigation indication: N/A
Usual Dose: Oral 300 mg/day.
Adverse Reaction: N/A
Pregnancy risk factor: N/A
Lactation: Contraindication in lactation.
Preparations: Tablets 150 mg\textsuperscript{NED}

- DIOSMINE

Indication: Disorders of the venous circulation, functional symptoms related to an acute hemorrhoidal episode.

Unlabeled/investigation indication: N/A
Usual Dose: Oral 2 tablets daily.
Adverse Reaction: Gastric discomfort, headache.

Pregnancy risk factor: N/A

Lactation: N/A

Preparations: Tablets 450 mg