UNILAB

Sodium Alginate
Sodium Bicarbonate
Calcium Carbonate

Kremil-S® COOL RELIEF

500 mg / 213 mg / 325 mg per 10 mL Oral Suspension
ANTACID

FORMULATION
Each 10 mL contains:
Sodium Alginate……..…….. 500 mg (as dry 425 mg)
Sodium Bicarbonate…….……..……..... 213 mg
Calcium Carbonate…….……..……..... 325 mg

PRODUCT DESCRIPTION
Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate
(Kremil-S® Cool Relief) is an off white or cream colored oral suspension with peppermint flavor.

WHAT IS IN THE MEDICINE?
This medicine contains sodium alginate, sodium bicarbonate, and calcium carbonate.

Sodium alginate, a natural polysaccharide, has been used for heartburn and acid reflux. It effectively provides physical barriers to acidic gastric contents and can significantly reduce reflux episodes.

Sodium bicarbonate and calcium carbonate are antacids that neutralize acid in the stomach. They are used to relieve acid indigestion and heartburn.

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the treatment of symptoms of gastroesophageal reflux such as acid regurgitation, heartburn, and indigestion due to reflux of stomach contents.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and children 12 years and older: Take 10 to 20 mL (1-2 sachets) after meals and before bedtime, up to four times a day.

Children 6 to 11 years old: Take 5 to 10 mL (1 sachet) after meals and before bedtime.
This product is not recommended for children under 6 years old.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to sodium alginate, sodium bicarbonate, calcium carbonate or to any ingredient in the product
- If you are on a low-sodium diet
- If you have congestive heart failure, renal failure, edema, or cirrhosis

UNDESIRABLE EFFECTS
Sodium Alginate
Immune system disorders: Anaphylactic reaction/shock
Respiratory, thoracic and mediastinal disorders: Bronchospasm
Gastrointestinal disorders: Flatulence
Skin and subcutaneous tissue disorders: Urticaria

Sodium Bicarbonate
Metabolism and nutrition disorders: Hypokalemia (low potassium levels in the blood), metabolic alkalosis (metabolic condition in which pH of tissue is elevated)
Cardiac disorders: Arrhythmia (irregular heartbeat)
Respiratory, thoracic and mediastinal disorders: Apnea (slow breathing)
Gastrointestinal disorders: Bloating, flatulence
General disorders and administration site conditions: Tiredness

Calcium Carbonate
Metabolism and nutrition disorders: Alkalosis (increase in blood pH), decreased appetite, hypercalcemia (too much calcium in the blood), metabolic alkalosis (metabolic condition in which pH of tissue is elevated), milk-alkali syndrome (high levels of calcium in the blood caused by taking too much calcium and absorbable alkali)
Nervous system disorders: Dizziness, headache
Gastrointestinal disorders: Burping, constipation, flatulence, nausea, rebound hyperacidity (added secretion of stomach acid), vomiting
General disorders and administration site conditions: Weakness

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- Sodium alginate may decrease the absorption of minerals such as calcium, zinc, manganese, chromium, and magnesium if used concomitantly.
- Antacids may interfere with the absorption of other medicines. It is advised that patients have an interval of at least two hours between taking a dose of an antacid and any other medicine.
- Antacids decrease the absorption of tetracyclines as a result of the chelation of the cation by the antibiotic. Doses of tetracyclines should be given 1 to 2 hours after taking antacids.
- Antacid-induced increases in urine pH may decrease excretion of weakly basic drugs (e.g., quinidine, chlorpromazine, propranolol, diazepam) and increase excretion of weakly acidic drugs (e.g., phenytoin, pentobarbital, warfarin).
- Absorption of buffered or enteric-coated aspirin is increased by simultaneous use of antacids.
- Antacid-induced changes in urine pH increase urinary excretion and decrease blood concentration of salicylates such as aspirin.
- Administration of sodium bicarbonate with naproxen increases the rate of naproxen absorption.
- Antacids also interact with enteric-coated tablets, capsules and granules. These products are formulated to resist gastric acid and dissolve in the more alkaline medium of the duodenum, releasing the drugs there. Enteric coatings may be disrupted prematurely in the presence of antacids, causing unwanted release of the drug in the stomach.
- Concomitant administration of antacids and orally administered digoxin, indomethacin, or iron salts may decrease the absorption of these drugs.
- Antacids can interact with fluoroquinolone antibacterials (e.g., ciprofloxacin, norfloxacin and ofloxacin) and penicillamine (for rheumatoid arthritis) to form insoluble metal ion chelates.
- The absorption of antifungals (e.g., ketoconazole, itraconazole) is reduced in the presence of antacids, as these drugs are less readily soluble in an alkaline than in an acid medium.
- Other drugs whose absorption is likely to be reduced in the presence of antacids include azithromycin, nitrofurantoin, rifampicin, phenytoin, chloroquine (to prevent malaria), phenothiazine antipsychotics (e.g., chlorpromazine for mental problems), and bisphosphonates (e.g., alendronate, etidronate, risedronate).

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose if still needed for the condition being treated and the subsequent doses at the recommended time or schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C. Do not refrigerate.
Store in original packaging.
Protect from light and moisture.
Keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE
The patient may feel bloated if he/she has taken more than the recommended dosage.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If overdose occurs, symptomatic treatment should be given.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Ask a doctor before use if you have hypercalcemia or nephrocalcinosis.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- Before taking this medication, tell your doctor:
  - If you have congestive heart failure or renal failure
  - If you have hypercalcemia or nephrocalcinosis
  - If your child is under 6 years old
- Stop use and ask a doctor if:
  - Symptoms worsen or do not improve after seven days

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at+632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Date of First Authorization: 07 July 2022
Date of Revision of PIL: May 2022
DRP-7065-01

Manufactured by GENUONE Sciences, Inc.
245, Sandan-gil, Jeonui-myeon, Sejong-si, Republic of Korea
Imported by **UNILAB, INC.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines
Distributed by UH Pharma, Inc.
3/F Building D, UL Corporate Center, No. 66 United Street
Mandaluyong City, Metro Manila, Philippines

Reg. IPOPHIL
ULC176816IN01

UNILAB Consumer Care
8-UNILAB-1
8-864522-1
Provincial Toll Free: 1-800-10-8645221
Email: info@unilab.com.ph
Website: www.unilab.com.ph

UNILAB
Trusted Quality Healthcare

129 x 245 mm