

UNILAB

HYOSCINE-N-BUTYLBROMIDE

Kremil-S SPASM RELIEF™

10 mg Film-Coated Tablet

Anticholinergic

FORMULATION

Each film-coated tablet contains:

Hyoscine-N-butylbromide 10 mg

PRODUCT DESCRIPTION

Hyoscine-N-butylbromide (Kremil-S Spasm Relief™) is a white, round, biconvex, film-coated tablet that is plain on both sides.

WHAT IS IN THE MEDICINE?

This product contains hyoscine-N-butylbromide, an antispasmodic which works by relaxing the smooth muscles found in the walls of the stomach, intestines and bile duct (gastrointestinal system) and the reproductive organs and urinary tract (genitourinary system). It reduces muscle contractions by preventing acetylcholine from acting on the muscle allowing the muscle to relax thus reducing painful spasms and cramps.

STRENGTH OF THE MEDICINE: Please see formulation.

WHAT IS THE MEDICINE USED FOR?

- For the symptomatic relief of abdominal pain, cramps and discomfort, including menstrual cramps, spasms of the gastrointestinal, biliary and urinary tracts
- For the relief of symptoms of irritable bowel syndrome

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Swallow the tablet whole with a full glass of water. Do not break, crush or chew the tablets.

Hyoscine-N-butylbromide should not be taken continuously for long periods of time.

Usual Recommended Adult Dose: 1 to 2 tablets 3 to 5 times a day (every 4 to 6 hours), up to a maximum of 6 tablets per day.

Usual Recommended Children (above 6 years old) Dose: 1 tablet 3 times a day

For symptoms of irritable bowel syndrome: Starting dose of 1 tablet 3 times a day, which may be increased to 2 tablets 4 times a day, if necessary.

Or, as directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to hyoscine-N-butylbromide or any ingredient in the product.
- If you have narrow-angle glaucoma (an eye problem), toxic megacolon (a very enlarged bowel), myasthenia gravis (a rare muscle wasting disease), obstructive prostatic hypertrophy (enlarged and blocked prostate), porphyria (hereditary blood disorder), tachyarrhythmia (a fast heart rate), and achalasia (a condition that causes difficulty in swallowing food)
- If you are pregnant, likely to become pregnant or breastfeeding
- Hyoscine-N-butylbromide must not be used when there is a blockage in the stomach or bowel or in certain conditions when there is reduced bowel activity.
- Hyoscine-N-butylbromide is generally not recommended in children below 6 years old

UNDESIRABLE EFFECTS

Cardiovascular: Flushing, decreased blood pressure, increased heart rate

CNS: Dizziness, nausea (feeling sick), hallucination (seeing, feeling or hearing things that are not there), dystonia (unusual muscle tone causing distortion of the body), confusion, agitation, coma

Dermatological: Dyshidrosis (outbreaks of sweat and dryness of skin), reduced ability to sweat, small blisters on hands and feet

Gastrointestinal: Dry mouth, diarrhea

Genitourinary: Inability to pass urine, problems emptying the bladder

Respiratory: Dyspnea (difficulty breathing)

Sensitivity Reaction: Allergic reactions (e.g., hives, rash, skin redness, itching, urticaria), anaphylactic shock, angioedema (swelling of the lips), difficulty in breathing (usually in patients who suffer with asthma or allergy)

Special Senses: Blurred vision, mydriasis (pupil dilation), increased eye pressure

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

- Medicines for depression (e.g., amitriptyline, clomipramine, doxepin, monoamine oxidase inhibitors such as selegiline)
- Medicines for allergies and motion sickness (e.g., meclizine)
- Medicines for severe mental illness (e.g., haloperidol or fluphenazine)
- Medicines for breathing problems (e.g., tiotropium and ipratropium)
- Medicines to control your heart rate (e.g., quinidine, procainamide or disopyramide)
- Medicines for Parkinson's disease and flu (e.g., amantadine, levodopa)
- Medicine for fungal infection (e.g., ketoconazole)
- Medicine for malaria (e.g., quinine)
- Other medicines with anticholinergic effects (e.g., glutethimide, pethidine)
- Other gastrointestinal medicines (e.g., cisapride, domperidone, metoclopramide)
- Antacids may decrease the absorption of hyoscine-N-butylbromide.
- Do not drink alcohol. Alcohol may increase the likelihood of side effects such as drowsiness.

Tell your doctor about all medicines you are taking including supplements and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose as needed. Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C. Keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Signs of overdose may include drowsiness, dry mouth, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, fast heart rate, and sight disturbances.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Ask a doctor before use if you have:

- A very fast heart rate or any heart problem
- You have a problem with your thyroid gland such as an overactive thyroid gland
- Difficulty or pain passing urine such as men with prostate problems
- Reflux esophagitis or ulcerative colitis
- Constipation
- Fever
- Previously been treated by a doctor for severe sweating disorder

This medicine may cause blurred vision and so may affect your ability to drive or operate machinery safely. If affected, do not drive or operate machinery.

- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Stop use and immediately consult a doctor if the following occur:

- Allergic reactions (e.g., skin rash and itching; swelling of the face, lips, tongue or other parts of the body; and sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock)
- If you experience red and painful eye and loss of vision or blurred vision. These symptoms may be caused by an increased pressure inside the eyeball and require urgent medical advice.
- If you have unexplained abdominal pain which persists or worsens or occurs with fever, nausea (feeling sick), vomiting (being sick), changes in your bowel movements, abdominal tenderness, blood in the stool, feeling faint, or low blood pressure (e.g., lightheadedness).
- If the pain is severe or does not improve within 48 hours of taking hyoscine-N-butylbromide. Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.

ADVERSE DRUG REACTION REPORTING STATEMENT

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.

AVAILABILITY

Hyoscine-N-butylbromide (Kremil-S Spasm Relief™) 10 mg Film-Coated Tablet in Alu-Clear PVC Blister Pack x 20's & 4's (Box of 100's and 4's)

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