IBUPROFEN+PARACETAMOL

ALAXAN® 200 mg / 325 mg TABLET
ALAXAN® FR 200 mg / 325 mg CAPSULE

Non-steroidal Anti-inflammatory Drug / Analgesic-Antipyretic

FORMULATION

Each tablet/capsule contains: Ibuprofen.....200 mg
Paracetamol.....325 mg

PRODUCT DESCRIPTION

Ibuprofen + Paracetamol (Alaxan® Tablet) is a round, two-layered, flat, beveled-edge tablet, debossed with "Alaxan" on the orange layer and plain on the white layer.

Ibuprofen + Paracetamol (Alaxan® FR Capsule) comes as a hard gelatin capsule. The cap is salmon pink opaque while the body is ivory opaque in color and printed with "Alaxan".

WHAT IS IN THE MEDICINE?

The product contains a combination of Ibuprofen and Paracetamol. Ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (also known as NSAIDs). Like other NSAIDs, Ibuprofen works by changing the body's chemical response to pain, swelling and fever resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain and/or fever. Paracetamol is a fever reducer and pain reliever.

The combination of Ibuprofen and Paracetamol has a synergistic effect, i.e., they work together to improve overall effect. The anti-inflammatory activity of Ibuprofen + Paracetamol combination is greater compared with each individual ingredient. Pain relief is also improved with the combination.

STRENGTH OF THE MEDICINE

Each Ibuprofen + Paracetamol (Alaxan® Tablet and Alaxan® FR Capsule) contains 200 mg Ibuprofen and 325 mg Paracetamol.

WHAT IS THE MEDICINE USED FOR?

- Ibuprofen + Paracetamol (Alaxan® and Alaxan® FR) is used for the relief of mild to moderately severe pain of musculoskeletal origin such as muscle pain (myalgia), arthritis, rheumatism, sprain, strain, bursitis (inflammation of the fluid-filled sac or bursa that lies between a tendon and skin), tendonitis, backache, and stiff neck.
- Ibuprofen + Paracetamol (Alaxan® and Alaxan® FR) is also used for the relief of tension headache, dysmenorrhea, toothache, pain after tooth extraction and minor surgical operations.
- Ibuprofen + Paracetamol (Alaxan® and Alaxan® FR) is effective for fever reduction.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Like other NSAIDs, the lowest effective dose of Ibuprofen + Paracetamol should be used for the shortest possible time.
This medicine is given orally (by mouth).

Adults and Children 12 years and older: 1 tablet or capsule every 6 hours as needed or as directed by a doctor.
Do not take more than directed.
Do not take longer than 10 days, unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take this medicine:

- If you are allergic to Paracetamol, Ibuprofen, Aspirin, and other NSAIDs. Ibuprofen, like other NSAIDs, may cause severe allergic reactions. Symptoms may include:
  - Hives (elevated, whitish or reddish patches on the skin with severe itching or prickling sensations)
  - Shock (anaphylactic) (a hypersensitivity reaction resulting in generalized skin lesions and itchiness, followed by low blood pressure and often accompanied by difficulty of breathing)
  - Facial swelling
  - Skin reddening
  - Asthma (wheezing)
  - Skin rash
  - Skin blisters
- If you have or have ever had kidney disease.
- If you develop signs and symptoms of liver abnormality (e.g., jaundice), stop taking this medicine and consult a doctor.
- Right before or after heart surgery
- If you have a history of stroke, heart attack, uncontrolled high blood pressure, or congestive heart failure
- If you have bronchospasm (constriction of air passages of the lung), angioedema (rapid swelling that occurs in the tissue just below the surface of the skin), nasal polyps or allergic-type reactions after taking Aspirin or other NSAIDs.
- If you are pregnant or breastfeeding unless advised by your doctor. It is especially important not to use an NSAID-containing product (e.g., Ibuprofen) during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

UNDESIRABLE EFFECTS

Ibuprofen + Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of undesirable effects. No serious undesirable effects have been reported to date. Only minor allergic type reactions such as skin rashes which are expected with other NSAIDs (e.g., Aspirin, Naproxen, etc.) have been reported.

Ibuprofen shares the same undesirable effects as other NSAIDs.

Ibuprofen may cause stomach and intestinal undesirable effects such as ulceration and/or bleeding; other undesirable effects are indigestion, heartburn, nausea, vomiting, eating disorder (anorexia), diarrhea, constipation, mouth ulcers (stomatitis), flatulence, bloating, and abdominal pain.

Ibuprofen may also cause harmful effects to the kidney and the liver.

There have been occasional reports of undesirable effects involving the blood and blood-forming tissues.

There have also been occasional reports of dizziness, drowsiness, general ill feeling (malaise), lightheadedness, nervousness, headache, fatigue, mood swings (emotional lability), loss of sensation (paresthesia), hallucinations, and dream abnormalities.

Ibuprofen may cause undesirable effects involving the ears and eyes such as ringing in the ears (tinnitus), decreased hearing, loss of visual sharpness (amblyopia), inflammation or infection of the membrane lining the eyelids (conjunctivitis), inflammation of the optic nerve (optic neuritis), double vision (diplopia) and cataracts.

Skin rashes have been observed. There have been rare reports of Stevens-Johnson Syndrome, Lyell's syndrome, and erythema multiforme which are serious types of allergy and may occur without warning. Symptoms of these serious types of allergy include multiple skin lesions, itching, fever, and joint pains.

Allergic reactions manifested as a syndrome of abdominal pain, fever chills, nausea and vomiting have occasionally occurred. Whole-body allergic reaction (anaphylaxis), constriction of air passages of the lung, dry mouth, gingival ulceration, and stuffy nose (rhinitis) have also been reported.

Other undesirable effects are fluid retention, increased blood pressure, low blood pressure, cerebrovascular accident (stroke) and palpitations.

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

- Aspirin decreases the amount of Ibuprofen in the blood, while Phenylbutazone, Indomethacin, Salicylates, and other NSAIDs (e.g., Mefenamic Acid, Naproxen, Diclofenac, Indomethacin, Ketoprofen) increase the risk of stomach and intestinal bleeding in patients receiving Ibuprofen.
- When taken with blood thinning (anticoagulant) medicines (e.g., Warfarin, Dicumarol) or together with thrombolytic agents (e.g., Streptokinase), Ibuprofen may cause stomach and intestinal bleeding.
- Ibuprofen increases the amount of lithium in the blood, interfering with lithium elimination in the kidney.
- Ibuprofen may cause acute reduction in kidney function and blood pressure response to ACE inhibitors (e.g., Captopril, Enalapril)
- Ibuprofen may reduce the effect of diuretics such as Furosemide and Thiazide.
- Medicines which stimulate the enzymes responsible for the metabolic activation of Paracetamol such as medicines for convulsion (e.g., Phenobarbital) may increase susceptibility to the harmful effects to the liver.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you missed a dose, take the next dose if still needed for pain and/or fever or inflammation and the subsequent dose every 6 hours thereafter.
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

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

SIGNS AND SYMPTOMS OF OVERDOSAGE

Overdosage of Paracetamol usually involves 4 phases with the following signs and symptoms:

I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure
IV. Recovery or progression to fatal complete liver failure

The most frequently reported symptoms of Ibuprofen overdose include abdominal pain, nausea, vomiting, fatigue (lethargy) and drowsiness. Other symptoms include headache, ringing in the ears (tinnitus), brain depression, and convulsions. Excessive acidity of the blood (metabolic acidosis), coma, acute kidney failure and absence of spontaneous breathing (apnea) may rarely occur.

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

If you have taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- This medicine should be given with care to patients with kidney or liver disease including patients taking other drugs that affect the liver.
- Do not use with any other product containing Paracetamol, Ibuprofen or other NSAIDs. If you are taking cough and cold preparations, other fever reducers or pain relievers, check if they contain Paracetamol (or Acetaminophen), Ibuprofen or other NSAIDs.
- Do not take more than the recommended dose or duration of treatment.
- This medicine may cause stomach bleeding. The chance is higher if you:
  - Are 60 years old or older
  - Have had stomach ulcers or bleeding problems
  - Take a blood thinning (anticoagulant) (e.g., Warfarin) or steroid (e.g., Prednisone) drug
  - Take other drugs containing an NSAID (e.g., Aspirin, Naproxen, or others)
  - Have 3 or more alcoholic drinks every day while using this product
  - Take more than the recommended dose or take more than the directed duration of treatment
- If stomach upset occurs, take this medicine with food or milk.
- Long term continuous use may increase the risk of heart attack or stroke.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you have :

- Problems or serious undesirable effects from taking pain relievers or fever reducers
- Stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- Ulcers
- Bleeding problems
- High blood pressure
- Heart or kidney disease
- Taken a medicine to help reduce the amount of water in the body (diuretic)
- Reached age 60 years or older

Ask a doctor before use if you are:

- Taking any other drug containing an NSAID such as Aspirin, Naproxen, Mefenamic Acid and others
- Taking a blood thinning (anticoagulant) or steroid (e.g. Prednisone) medicine
- Under a doctor's care for any serious condition
- Taking any other drug

Stop use and ask a doctor if:

- You feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- Pain gets worse or lasts more than 10 days
- Fever gets worse or lasts more than 3 days
- Stomach pain or upset gets worse or lasts
- Any new symptoms appear

If you are pregnant or breastfeeding, ask a doctor before use.

AVAILABILITY

Ibuprofen + Paracetamol (Alaxan® Tablet) available in Box of 10's and 500's (in Blister Foil x 10's)
Ibuprofen + Paracetamol (Alaxan® FR Capsule) available in Box of 10's and 100's (in Blister Foil x 10's)

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): May 2010

UNILAB
Trusted Quality Healthcare

Manufactured by PT MEDIFARMA LABORATORIES
Jl. Raya Jakarta - Bogor Km. 33, Kel. Curug
Kec. Cimanggis, Kota Depok, Jawa Barat, Indonesia
Imported and Distributed by UNILAB, Inc.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

ULC153261IN02

Reg. IPOPHIL

PARACETAMOL
BIOGESIC®

500 mg Tablet
Analgesic - Antipyretic

FORMULATION
Each tablet contains: Paracetamol.....500 mg

PRODUCT DESCRIPTION
Paracetamol (Biogesic®) 500 mg Tablet is an orange, convex, 0.662" x 0.300" in diameter, plain, elliptical tablet, embossed with "BIOGESIC" on one side and "500" insignia on the other side.

WHAT IS IN THE MEDICINE?
This product contains paracetamol, a fever reducer and pain reliever.

STRENGTH OF THE MEDICINE See Formulation.

WHAT IS THE MEDICINE USED FOR?
- For the relief of minor aches and pains such as headache, backache, menstrual cramps, muscular aches, minor arthritis pain, toothache, and pain associated with the common cold and flu
- For fever reduction

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and Children 12 years and older: Orally, 1 to 2 tablets every 4 to 6 hours, as needed for pain and/or fever, or, as directed by a doctor.
- Do not take more than 4 g (8 tablets) in each 24-hour period.
- Do not use more than the recommended dose.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If the patient is allergic to paracetamol or any ingredient in the product
- Avoid long-term use of paracetamol in patients with anemia or with heart, lung, kidney, or liver disease.

UNDESIRABLE EFFECTS
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.
Skin rashes, hypersensitivity reactions, changes in the number of white blood cells and platelets, and minor stomach and intestinal disturbances have been reported.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- The absorption of paracetamol may be accelerated by metoclopramide or domperidone and absorption reduced by cholestyramine.
- Medicines which stimulate the enzymes responsible for the metabolic activation of paracetamol such as medicines for convulsion (e.g., phenobarbital) may increase susceptibility to the harmful effects to the liver.
- Warfarin, a blood thinning medicine; an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using paracetamol and warfarin at the same time. Paracetamol increases the anticoagulation effect of warfarin.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, take the next dose if still needed for pain and/or fever and the subsequent dose every 4 to 6 hours thereafter.
Do not double the dose

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of sight and reach of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Overdosage of paracetamol usually involves 4 phases with the following signs and symptoms:
I. Eating disorder, nausea, vomiting, malaise, and excessive sweating;
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output;
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure;
IV. Recovery or progression to fatal complete liver failure

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE
If more than the recommended dosage has been given, consult a doctor or contact a Poison Control Center right away. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms because of the risk of delayed, serious liver damage.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- **Liver Warning.** This product contains paracetamol. Severe liver damage may occur if:
  - > An adult or child 12 years old and above takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount;
  - > Taken with other medicines containing paracetamol (or acetaminophen);
  - > An adult has 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains paracetamol, ask a doctor.
- Ask a doctor before use if the patient has kidney or liver problems.
- Ask a doctor before use if the patient is taking warfarin, a blood thinning medicine.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
- If you are pregnant or breastfeeding, consult your doctor before use.
- Stop use and ask a doctor if:
  - > New symptoms occur
  - > Symptoms do not get better
  - > Redness or swelling is present
  - > Fever gets worse or lasts more than 3 days
  - > Pain gets worse or lasts more than 10 days

AVAILABILITY: In Box of 500's (blister strips x 20's) and box of 10's (blister strips x 10's)
DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): April 2014

Reg. IPOPHIL ULC156168IN02

Manufactured by PT Medifarma Laboratories
Jl. Raya Jakarta - Bogor Km. 33, Kel. Curug, Kec. Cimanggis
Kota Depok, Jawa Barat, Indonesia
Imported and Distributed by **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Trusted Quality Healthcare

Phenylpropanolamine HCl
Chlorphenamine Maleate
Paracetamol

Decolgen® Forte

25 mg / 2 mg / 500 mg TABLET
Nasal Decongestant / Antihistamine / Analgesic-Antipyretic

FORMULATION

Each tablet contains:

Phenylpropanolamine HCl	25 mg
Chlorphenamine Maleate	2 mg
Paracetamol	500 mg

PRODUCT DESCRIPTION

Phenylpropanolamine HCl + Chlorphenamine Maleate + Paracetamol (Decolgen® Forte) tablet is a yellow, round, convex tablet with Westmont insignia on one side and flat, plain, bevel-edged on the other side.

WHAT IS IN THE MEDICINE?

This medicine contains Phenylpropanolamine HCl, Chlorphenamine Maleate and Paracetamol.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed and congested air passages making breathing easier. It decongests stuffy nose and clogged nasal sinuses.
Chlorphenamine Maleate, an anti-allergy, relieves symptoms of allergy such as runny nose, sneezing, and itchy, watery eyes.
Paracetamol is an effective fever reducer and pain reliever.

STRENGTH OF THE MEDICINE See Formulation

WHAT IS THIS MEDICINE USED FOR?

This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adults and children 12 years and older: Orally, 1 tablet every 6 hours, or, as recommended by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient in the product
- If you have high blood pressure or severe heart disease unless recommended by a doctor
- If you have anemia, kidney or liver disease unless recommended by a doctor
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS

Phenylpropanolamine may cause sudden, persistent, severe headache, nervousness, restlessness, insomnia/sleeplessness, dizziness, anxiety, confusion, high blood pressure, palpitation, chest tightness, tremor, agitation, irritability, aggressiveness (particularly in young children), nausea, and blurred vision.
Chlorphenamine Maleate may cause sleepiness and drowsiness. Other undesirable effects include muscle weakness, gastrointestinal discomfort, nausea, vomiting, diarrhea or constipation, dryness of the mouth, nose, and throat, difficulty urinating, ringing in the ears, visual disturbance, blurred vision, insomnia/sleeplessness, tremor, nervousness, irritability, chest tightness, increased or decreased blood pressure, and headache.
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects. Skin rashes and minor stomach and intestinal disturbances have been reported.

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

Do not use this product together with sympathomimetic agents (e.g., Epinephrine, etc.) and general anesthetics (e.g., Halothane, etc.) because of the possibility for increased toxicity.
Concurrent administration with medicines for depression (e.g., Amitriptyline, Imipramine, Sertraline, Moclobemide, etc.) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).
The absorption of Paracetamol may be accelerated by Metoclopramide or Domperidone and reduced by Cholestyramine.
Medicines which stimulate the enzymes responsible for the metabolic activation of Paracetamol such as medicines for convulsion (e.g., Phenobarbital, etc.) may increase susceptibility to the harmful effects to the liver.

Warfarin, a blood thinning medicine; an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using paracetamol and warfarin at the same time. Paracetamol increases the anticoagulation effect of warfarin.
Tell your doctor about other medicines you are taking, especially other medicines for cough, cold, allergy, pain, or fever.

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 (i.e., every 6 hours).
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

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

SIGNS AND SYMPTOMS OF OVERDOSAGE

Phenylpropanolamine HCl

Fast heart rate (tachycardia); Irregular heart beat (arrhythmia); High blood pressure; Excitation; Seizures; Enlargement of the pupils; Cases of heart attack, stroke, intracranial bleeding/cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain), and death have also been reported

Chlorphenamine Maleate

Extreme sleepiness or prolonged drowsiness; Weakness; Hallucination; Convulsion; Agitation; Irritability; Tachycardia; Coma

Paracetamol

Overdosage of Paracetamol usually involves 4 phases with the following signs and symptoms:

I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure
IV. Recovery or progression to fatal complete liver failure

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

If you have taken more than the recommended dosage, consult a doctor or contact a poison control center right away, even if you seem well, because of the risk of delayed, serious liver damage. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Use with caution in patients with high blood pressure, toxic goiter, benign prostatic hypertrophy, heart rate irregularity, glaucoma, and in those taking antidepressants.
- Patients with heart disease and uncontrolled/untreated high blood pressure should consult a doctor prior to taking Phenylpropanolamine.

- ***Liver Warning:*** This product contains Paracetamol. Severe liver damage may occur if you take:
  - More than 4 g of Paracetamol in 24 hours, which is the maximum daily amount;
  - With other medicines containing Paracetamol (or acetaminophen);
  - 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing Paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains Paracetamol, ask a doctor.
- Ask a doctor before use if the patient has liver or kidney disease.
- Ask a doctor before use if the patient is taking warfarin, a blood thinning medicine.
- May cause drowsiness; patients should observe caution while driving or performing other tasks requiring alertness.
- 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:
  High blood pressure or any type of heart problems; Glaucoma; Thyroid problems; Diabetes; Liver or kidney disease; An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if: Fever gets worse or lasts more than 3 days; New symptoms occur

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

UNILAB
Trusted Quality Healthcare

AVAILABILITY:

In box of 100's (blister pack of 20's)

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL):

December 16, 2016

ULC155673IN01 Reg. IPOPHIL

Manufactured by PT. Medifarma Laboratories
Jl. Raya Jakarta -Bogor Km. 33, Kel. Curug, Kec., Cimanggis
Kota Depok, Jawa Barat, Indonesia
Imported and Distributed by **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Loperamide

Diatabs®

2 mg CAPSULE

ANTIMOTILITY

FORMULATION
Each capsule contains:Loperamide (as Hydrochloride) ..... 2 mg

PRODUCT DESCRIPTION Diatabs Capsule has a dark green opaque cap and ivory opaque body.

WHAT IS IN THE MEDICINE?
This medicine contains loperamide, an antidiarrheal agent which slows intestinal movement and reduces fluid and salt loss in the intestines, resulting in improved stool consistency.

STRENGTH OF THE MEDICINE Please see formulation

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the following conditions:
- Control and symptomatic relief of:
  - acute non-specific diarrhea
  - chronic diarrhea associated with inflammatory bowel disease
- Reduction of number and volume of discharge in patients with ileostomies and colostomies

In addition to using loperamide for diarrhea, it is important that you replace the fluid and salt loss with the use of oral rehydration solutions (ORS) and/or by drinking plenty of fluids.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
- **For Symptomatic Relief of Acute Diarrhea**

Adult Dose: Take 2 capsules initially followed by 1 capsule after each loose bowel movement.
Or, as directed by a doctor.
Maximum dose is 16 mg (8 capsules) per day.
Discontinue if there is no improvement after 2 days.

- **For Symptomatic Relief of Chronic Diarrhea**

Adult Dose: Take 2 capsules initially followed by 1 capsule after each loose bowel movement.
Then reduce loperamide dose to meet individual requirements. When the optimal daily dosage has been established, administer this amount as a single dose or in divided doses.
Or, as directed by a doctor.

Average Daily Maintenance Dose: Take 2 to 4 capsules/day. A dosage of five capsules (10 mg) is rarely exceeded.
If no clinical improvement is observed after treatment with 8 capsules/day (16 mg/day) for at least 10 days, symptoms are unlikely to be controlled by further loperamide administration.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to loperamide or any ingredient in the product
- If it is for a child under 12 years old
- If you are pregnant or breastfeeding
- If you are constipated and also in whom constipation should be avoided (e.g., diarrhea resulting from infections)
- If your abdomen is swollen or you have abdominal pain
- If you have acute dysentery which is characterized by blood in stools and high fever
- If you have pseudomembranous colitis (diarrhea associated with antibiotics), active ulcerative colitis, meningitis, or a history of liver disease

UNDESIRABLE EFFECTS
Loperamide is generally well tolerated; however, dry mouth, abdominal pain, distention or discomfort, nausea, vomiting, fatigue, flatulence, dyspepsia, constipation, epigastric pain, paralytic ileus (temporary absence of intestinal movement), and toxic megacolon (rapid widening of the colon accompanied by infection or inflammation) may occur. Loperamide may rarely cause drowsiness and dizziness.
Allergic reactions including unexplained wheezing, shortness of breath, passing out, or swelling of the face and throat have occurred very rarely.
Undesirable effects involving the skin include pruritus (itch), rash, urticaria (hives) and extremely rare cases of angioedema (rapid swelling beneath the skin) and bullous (large skin blister) eruption including Stevens-Johnson syndrome, erythema multiforme, and toxic epidermal necrolysis (severe allergic reactions characterized by separation or exfoliation of tissue) have been rarely reported.

WHAT OTHER MEDICINES OR FOODS SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- Concomitant administration with the following may result in increased loperamide plasma levels:
  - Ritonavir (used to treat Human Immunodeficiency Virus)
  - Quinidine (used to treat abnormal heart rhythms)
  - Oral desmopressin (used to treat excessive urination)
  - Itraconazole or ketoconazole (used to treat fungal infections)
  - Gemfibrozil (used to lower cholesterol)
- Medicines that slow down the action of the stomach and intestines (e.g., some medicines for depression and cold and allergy medications) as these may increase the constipating effect of loperamide
- Medicines that cause drowsiness since loperamide may also cause drowsiness

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose if still needed for diarrhea. Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of reach and sight of children. Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Loperamide overdose may result in constipation, central nervous system (CNS) depression (e.g., drowsiness and dizziness), paralytic ileus (temporary absence of intestinal movement), and urinary retention (decreased urination).
In adults, reported overdosage within 24 hours resulted in nausea after 40 mg (20 capsules) and vomiting after 60 mg (30 capsules).

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE
If you have taken more than the recommended dosage (i.e., more than 8 capsules per day), consult a doctor or a Poison Control Center right away.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.
- Keep out of reach and sight of children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Stop use and consult your doctor if:
- Any undesirable effect occurs or acute diarrhea persists for more than two days, if symptoms worsen, if abdominal swelling or bulging develops, or if fever develops.
- You have Acquired Immune Deficiency Syndrome (AIDS) and any signs of abdominal swelling or bulging. There have been isolated reports of toxic megacolon (rapid widening of the colon accompanied by infection or inflammation) in AIDS patients treated with loperamide.

A serious condition may develop if too much fluid has been lost by the body due to diarrhea. Consult a doctor if any of the following conditions develop:
- Decreased urination
- Dizziness and lightheadedness
- Dryness of mouth
- Increased thirst
- Wrinkled skin

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY Available in box of 100's and 500's (Foil strip x 4's), Foil strip x 4's per envelope

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): November 2018
DATE OF FIRST AUTHORIZATION: 15 March 1999

UNILAB

Trusted Quality Healthcare

DR-XY24964
Reg. IPOPHIL

Manufactured by **UNILAB, Inc.**
No. 66 United St., Mandaluyong City, Metro Manila, Philippines

P300000024108

Aluminum Hydroxide
Magnesium Hydroxide
Simeticone

Kremil - S® Tablet

178 mg/233 mg/30 mg Chewable Tablet

ANTACID / ANTIFLATULENT

FORMULATION

Each chewable tablet contains:

Aluminum Hydroxide.....178 mg
Magnesium Hydroxide .....233 mg
Simeticone .....30 mg

PRODUCT DESCRIPTION

Kremil-S Chewable Tablet is a light pink, round, speckled, tutti-frutti flavored chewable tablet with "Kremil" engraved on one side and plain on the other.

WHAT IS IN THE MEDICINE?

This product contains a combination of antacids, Aluminum Hydroxide and Magnesium Hydroxide, which effectively increase gastric pH by neutralizing the acid produced in the stomach.
This product also contains Simeticone, a water-repellant with low surface tension used to relieve bloating and gassiness by causing small bubbles to coalesce to large bubbles, which are passed more easily.

STRENGTH OF THE MEDICINE

Please see formulation.

WHAT IS THE MEDICINE USED FOR?

- For the symptomatic relief of hyperacidity associated with peptic ulcer, gastritis, esophagitis, and dyspepsia.
- As an antiflatulent to alleviate the symptoms of gassiness, including postoperative gas pain, associated with hyperacidity.
- As adjunct to H2-blockers or proton pump inhibitors for the rapid relief of ulcer symptoms.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Tablet may be chewed then swallowed without water or swallowed whole with water.
Recommended Adult Dose: 1 to 2 tablets to be taken one hour after each meal and at bedtime.
Or, as prescribed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Allergy to any ingredient in the product
If you have:

- Kidney disease
- Intestinal obstruction
- Appendicitis
- Fecal impaction
- Gastric outlet obstruction
- Constipation
- Phosphate depletion and low serum phosphate
- Osteomalacia (softening of the bones)

UNDESIRABLE EFFECTS

The combination of Aluminum Hydroxide and Magnesium Hydroxide balances the side effects of diarrhea from Magnesium Hydroxide and constipation from Aluminum Hydroxide.
Excessive doses of Aluminum Hydroxide and Magnesium Hydroxide may result in high Aluminum and Magnesium levels in the blood in patients with kidney impairment.

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

Antacids decrease the absorption of Tetracycline and Iron. Take Tetracycline 1 hour before or 2 hours after antacids and 2 hours before or 3 hours after Iron-containing preparations.
Antacids may decrease the absorption of orally administered Digoxin, or Indomethacin, Isoniazid, Quinolones (e.g., Ciprofloxacin, Ofloxacin), Ketoconazole. Doses of these drugs should be spaced as far apart as possible from doses of antacids.
Antacid-induced changes in urine pH increase urinary excretion and decrease blood concentration of salicylates such as Aspirin.
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).
Aluminum-Magnesium antacid combination is reported to increase the absorption of Dicumarol, Diazepam and Pseudoephedrine.
Magnesium and Aluminum Hydroxide administration may decrease the rate of Chlordiazepoxide absorption.
Antacids reduce the bioavailability of bisphosphonates (e.g., Alendronate, Etidronate, Risedronate).

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just give the next dose and the subsequent doses at the recommended time or schedule.
Do not double the dose unless recommended by a doctor.

HOW SHOULD YOU KEEP THIS MEDICINE?

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

SIGNS AND SYMPTOMS OF OVERDOSAGE

Aluminum Hydroxide may accumulate in bones, lungs and nerve tissues in patients with kidney failure. Large doses or chronic use of Aluminum may also cause phosphorus depletion which is characterized by anorexia, malaise, and muscle weakness. Prolonged use may cause kidney stones, osteomalacia (softening of the bones) and osteoporosis.
Hypotension, nausea, vomiting, ECG change, respiratory or mental depression, and coma have also been reported with large doses of Magnesium in patients with severe kidney disease.
Simeticone overdosage is not expected to cause any clinically important effects.

WHAT TO DO IF 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

Patients with advanced kidney disease are at risk of Aluminum and Magnesium accumulation and toxicity. Do not use these products in such patients.
Do not use after the expiry date on the label.
Phenylketonurics: This product contains Phenylalanine as one of the metabolites of Aspartame.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you are:

- Pregnant or breastfeeding
- Taking other medicines; antacids may interact with certain medicines.

Stop use and ask a doctor if you need to take this product for more than 14 days.

Availability: Box of 4's, 100's and 500's (in flex foil of 4's)

Date of Revision of Patient Information Leaflet (PIL): July 29, 2009

Trusted Quality Healthcare

Manufactured by **UNITED LABORATORIES, INC.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines
For **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Reg. IPOPHIL P30000012542

DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL

TUSERAN® FORTE

15 mg / 25 mg / 325 mg Capsule
Antitussive / Nasal Decongestant / Analgesic - Antipyretic

FORMULATION
Each capsule contains:
Dextromethorphan Hydrobromide, USP ……15 mg
Phenylpropanolamine Hydrochloride ……25 mg
Paracetamol……..325 mg

PRODUCT DESCRIPTION
Dextromethorphan HBr + Phenylpropanolamine HCl + Paracetamol (Tuseran® Forte) is a hard gelatin capsule with gray opaque cap, printed with "Medichem" logo and yellow opaque body printed with "TUSERAN FORTE"

WHAT IS IN THE MEDICINES?
This medicine contains dextromethorphan HBr, phenylpropanolamine HCl and paracetamol.
Dextromethorphan HBr, an antitussive, suppresses the area in the brain that causes coughing.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.
Paracetamol is an effective fever reducer and pain reliever.

STRENGTH OF THE MEDICINE
See Formulation

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the relief of cough, clogged nose, postnasal drip, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and Children 12 years and older: Orally, 1 capsule every 6 hours, or as recommended by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to any ingredient of the product
- If you have high blood pressure or severe heart disease unless recommended by a doctor
- If you have anemia, kidney or liver disease unless recommended by a doctor
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS
Adverse effects with dextromethorphan are rare and include nausea, vomiting, stomach discomfort, constipation, dizziness, drowsiness, excitation, and mental confusion.

Hypersensitivity reactions have also been reported.

Phenylpropanolamine HCl may cause sudden, persistent, severe headache, nervousness, restlessness, insomnia/sleep disturbance, dizziness, anxiety (feeling of uneasiness), confusion, high blood pressure, palpitation, chest tightness, tremor, agitation, irritability, aggressiveness (particularly in young children), nausea, and blurred vision.

Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects. Skin rashes, hypersensitivity reactions, changes in the number of white blood cells and platelets, and minor stomach and intestinal disturbances have been reported. Rare cases of serious skin reactions (i.e., Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis) have also been reported.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Do not use this product together with sympathomimetic agents (e.g., epinephrine) and general anesthetics (e.g., halothane) because of the possibility for increased toxicity.

Concurrent administration with monoamine oxidase (MAO) inhibitors (e.g., selegiline, moclobemide) and tricyclic antidepressants (e.g., amitriptyline, imipramine) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).

Combined use of phenylpropanolamine and caffeine may produce an additive increase in blood pressure. Severe, life threatening, and occasionally fatal hypertensive reactions have been reported.

Dextromethorphan is primarily metabolized by the cytochrome P450 isoenzyme CYP2D6. There is a possibility of interaction with inhibitors of this enzyme, including amiodarone, haloperidol, propafenone, quinidine, selective serotonin reuptake inhibitors (SSRIs), and thioridazine. Symptoms of dextromethorphan toxicity have been reported when used together with amiodarone and quinidine.

Additive central nervous system (CNS) depression may occur when dextromethorphan is taken together with alcohol, antihistamines, psychotropics and other CNS depressants.

Paracetamol, when used together with warfarin (a blood-thinning medicine), may cause an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding. Paracetamol increases the anticoagulation effect of warfarin.

Medicines which stimulate the enzymes responsible for the metabolic activation of paracetamol such as medicines for convulsion (e.g., phenobarbital, phenytoin) may increase susceptibility to the harmful effects to the liver.

The absorption of paracetamol may be accelerated by metoclopramide or domperidone and reduced by cholestyramine.

Tell your doctor about other medicines you are taking (i.e., other medicines for cough, cold, allergy, pain, or fever, especially other paracetamol-containing products).

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 (i.e., every 6 hours).

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30˚C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Dextromethorphan HBr
Acute overdosage of dextromethorphan may cause nausea, vomiting, drowsiness, dizziness, excitation, confusion, psychosis, CNS depression, stupor (decreased mental alertness), blurred vision, nystagmus (involuntary and rapid movement of the eyeball), dysarthria (slurred speech), respiratory depression, shallow respiration, ataxia (uncontrolled muscle movement), tremor, urinary retention, seizures, and coma.

Phenylpropanolamine HCl
Signs and symptoms of phenylpropanolamine overdosage include tachycardia, arrhythmia (irregular heart beat), high blood pressure, excitation, enlargement of the pupils. Cases of heart attack, stroke, intracranial hemorrhage/cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain), seizures, and death have also been reported.

Paracetamol
Overdosage of paracetamol usually involves 4 phases with the following signs and symptoms:
I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver failure (e.g., jaundice) and possibly kidney failure and cardiomyopathy (disorder of the heart muscle) may develop
IV. Recovery or progression to fatal complete liver failure

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor or contact a poison control center right away, even if you seem well, because of the risk of delayed, serious liver damage. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Use with caution in patients with high blood pressure, toxic goiter, benign prostatic hypertrophy, heart rate irregularity, glaucoma, and in those taking antidepressants.
- Patients with heart disease and uncontrolled/untreated high blood pressure should consult a doctor prior to taking phenylpropanolamine.

- **Liver Warning:** This product contains paracetamol. Severe liver damage may occur if:
  - An adult or child 12 years and older takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount;
  - Taken with other medicines containing paracetamol (or acetaminophen);
  - An adult has 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing dextromethorphan, phenylpropanolamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
- Do not take this medicine if you are at risk of developing respiratory failure (e.g., those with chronic bronchitis, emphysema or during an asthma attack).
- Do not take this medicine if you have persistent or chronic cough (i.e., cough lasting for more than 3 weeks) or when coughing is accompanied by excessive secretions unless directed by a doctor.
- A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- May cause drowsiness and dizziness; patients should observe caution while driving or performing other tasks requiring alertness.
- Ask a doctor before use if you have liver or kidney disease.
- Ask a doctor before use if you are taking warfarin, a blood thinning medicine.
- 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:
  - High blood pressure or any type of heart problems
  - Glaucoma
  - Thyroid problems
  - Diabetes
  - Liver or kidney disease
  - An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if:
  - Fever gets worse or lasts more than 3 days
  - New symptoms occur

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: In box of 100's and envelope by 4's (foil strip x 4's)
DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): 15 March 2017
DATE OF REVISION OF FIRST AUTHORIZATION: 05 February 2003

Manufactured by United Laboratories, Inc.
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines
for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

Trusted Quality Healthcare

DR-XY16850 Reg. IPOPHIL P30000014050