UNILAB

Loperamide Simeticone

Diatabs® Advance

2 mg / 125 mg SOFTGEL CAPSULE
ANTI-DIARRHEAL/ANTI-FLATULENT

FORMULATION

Each softgel capsule contains:
Loperamide ..... 2 mg
Simeticone ..... 125 mg

PRODUCT DESCRIPTION

Red, oval, transparent soft gelatin capsule, with oily, pink liquid fill using the EmulsiFill™ technology. The EmulsiFill™ technology is a unique system that allows accurate filling of two drug-containing immiscible liquids into a capsule.

WHAT IS IN THE MEDICINE?

This medicine contains loperamide, an antidiarrheal agent which slows down intestinal movement and decreases fluid and salt loss in the intestines, resulting in improved stool consistency and reduced dehydration.

It also contains simeticone, an antiflatulent which relieves bloating and gassiness by lowering surface tension of gas bubbles in the gastrointestinal (GI) tract leading them to coalesce and be expelled.

The combination of loperamide and simeticone provides faster relief of both diarrhea and associated gas-related abdominal pain, cramps and bloating than loperamide or simeticone alone.

STRENGTH OF THE MEDICINE

See Formulation

WHAT IS THE MEDICINE USED FOR?

This medicine is used for the relief of symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to gas.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adults and Children 12 years and older:
Orally, 2 capsules after the first loose stool;
1 capsule after each subsequent loose stool;
but not more than 4 capsules in 24 hours, or as recommended by a doctor.

This medicine is not recommended for children below 12 years old.

DIRECTIONS FOR USE:

- Drink plenty of clear fluids to help prevent dehydration caused by diarrhea.
- Take only on an empty stomach (1 hour before or 2 hours after a meal).
- Take with a full (240 mL) glass of water.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to loperamide or simeticone or any ingredient in the product
- If your abdomen is swollen
- If you have abdominal pain in the absence of diarrhea
- If you have acute dysentery which is characterized by bloody stools and fever
- If you have pseudomembranous ulcerative colitis (diarrhea associated with antibiotics), acute ulcerative colitis (inflammation of the colon), bacterial enterocolitis (inflammation of the digestive tract resulting from bacterial infection such as *Salmonella*, *Shigella*, and *Campylobacter*)
- If a child is under 12 years old
- If you are constipated and in cases when constipation should be avoided (e.g., diarrhea resulting from infections)
- If you have difficulty swallowing

Loperamide + simeticone should not be used in medical conditions where slowing of the intestines should be avoided due to the possible risk of developing ileus (blockage of the intestine), megacolon (acute dilatation of the colon) and toxic megacolon (acute dilatation of the colon associated with infection or inflammation).
Loperamide + simeticone should be discontinued immediately when constipation, abdominal distension, or ileus (blockage of the intestine) develop.

UNDESIRABLE EFFECTS

Loperamide
The most frequently reported undesirable effects with loperamide include nausea, constipation, headache, abdominal cramps, dizziness, dry mouth, dysgeusia (altered taste), vomiting, flatulence, dyspepsia, drowsiness, fatigue urinary retention, difficulty urinating, abdominal pain, distension, or discomfort.

Immune system disorders: Anaphylactic shock (serious allergic reaction which causes difficulty in breathing or dizziness), angioedema (rapid swelling of the skin)
Nervous system disorders: Coordination abnormality, loss/depressed level of consciousness, stupor (decreased mental alertness)
Eye disorders: Miosis (constriction of the pupil of the eye)
Cardiac disorders: Cardiac arrest (stopping of heartbeat), QT interval prolongation, syncope (fainting/temporary loss of consciousness), *torsades de pointes*/ventricular arrhythmias (life-threatening irregular heartbeat)
Respiratory, thoracic and mediastinal disorders: Respiratory depression (slow, shallow or ineffective breathing), shortness of breath, unexplained wheezing
Gastrointestinal disorders: Glossodynia (burning sensation or pain around the tongue), paralytic ileus (obstruction of the intestine due to paralysis of the intestinal muscles), toxic megacolon (acute dilatation of the colon associated with infection or inflammation)
Skin and subcutaneous tissue disorders: Erythema multiforme (a skin condition characterized by symmetrical, red, raised skin areas all over the body), pruritus (itching), rash, serious skin reactions (i.e., Stevens-Johnson syndrome and toxic epidermal necrolysis) which may include symptoms such as reddening of the skin, rash, blisters, and detachment of the upper surface of the skin; urticaria (itchy rash)
Musculoskeletal and connective tissue disorders: Hypertonia (muscle stiffness

Simeticone
There have been no reports of undesirable effects after ingestion of simeticone. A very severe allergic reaction is rare. However, if you notice any undesirable effects, consult your doctor immediately.

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

Loperamide
- Concomitant administration with the following medicines may result in increased loperamide plasma levels:
  - o Ritonavir (used to treat Human Immunodeficiency Virus)
  - o Quinidine (used to treat abnormal heart rhythms)
  - o Clarithromycin or erythromycin (used to treat bacterial infections)
  - o Quinine (used to treat malaria)
  - o Itraconazole or ketoconazole (used to treat fungal infections)
  - o Gemfibrozil (used to lower cholesterol)
- Medicines that reduce the action of the stomach and intestines (e.g., antidepressants and cold and allergy medications) may increase the constipating effect of loperamide.
- Concomitant administration with oral desmopressin (used to treat excessive urination) may increase the plasma levels of desmopressin.
- Medicines that cause drowsiness since drowsiness may occur when diarrhea is treated with loperamide.

Simeticone
Reduce air swallowing by avoiding fizzy, carbonated drinks and food that may increase gas in the stomach.

Tell your doctor if you are taking other medicines, including herbal medicines and food supplements.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose if still needed for diarrhea 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.
- Protect from light.
- Keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Loperamide
Loperamide overdose may result in constipation, central nervous system (CNS) depression (e.g., near unresponsiveness), coordination abnormality, drowsiness, constriction of the pupil of the eye, muscle stiffness, respiratory depression), urinary retention, and paralytic ileus (obstruction of the intestine due to paralysis of the intestinal muscles). Patients with liver problems and children may be more sensitive to CNS effects.
Cardiac events such as QT interval prolongation, *torsades de pointes*/other serious ventricular arrhythmias (life-threatening irregular heartbeat), cardiac arrest (stopping of heartbeat), and syncope (fainting/temporary loss of consciousness) have been observed following loperamide overdose. Fatal cases have been also reported.

Reported overdosage within 24 hours resulted in nausea after 40 mg (20 capsules) and vomiting after 60 mg (30 capsules).

Simeticone
There have been no cases of overdosage reported with simeticone use.
If overdosage is suspected, consult a doctor immediately.

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 4 capsules per day), consult a doctor or contact a poison control center right away. Quick medical attention is important even if you do not notice any signs or symptoms.

Children may react more strongly to large amounts of loperamide + simeticone than adults.
If a child takes too much or shows any of the above symptoms, call a doctor immediately.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Although loperamide stops diarrhea, it will not treat the cause of it. Whenever possible, the cause of diarrhea should also be treated.
- Fluid and electrolyte depletion often occur in patients with diarrhea. Thus, appropriate fluid and electrolyte intake is very important. The use of loperamide does not substitute the need for appropriate fluid and electrolyte therapy.
- Patients with diarrhea should drink oral rehydration solution. Those with acute symptoms without signs of dehydration may drink plenty of water, clear fluids, unsweetened juices, or clear soups. Alcohol or milk should be avoided, as well as fruits, green vegetables, and spicy or fatty foods since they may worsen diarrhea and its symptoms.
- May cause loss/depressed level of consciousness, tiredness, dizziness, or drowsiness; patients should observe caution while driving or performing other tasks requiring alertness.
- Patients with Acquired Immunodeficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV) who are treated with loperamide + simeticone should stop therapy at the earliest signs of abdominal distension. There have been isolated reports of toxic megacolon in AIDS or HIV patients with infectious colitis from both viral and bacterial pathogens treated with loperamide.

- Loperamide should be used with caution in patients with liver impairment since
  - first-pass metabolism may be decreased in such patients and it may lead to CNS toxicity.
- Loperamide + simeticone should be used with special caution in young children and those with compromised blood brain barrier (e.g., meningitis) because of the greater variability of response in these groups. Dehydration, particularly in young children, may further influence the variability of response to loperamide + simeticone.
- Do not take this medicine for anything other than its intended use.
- Do not take more than the recommended dose. Serious health problems (e.g., fast or irregular heartbeat, stopping of heartbeat) may occur ***(See Signs and Symptoms of Overdosage)***.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you:
- Are pregnant or breastfeeding
- Are currently taking an anti-infective medicine
- Have fever
- Have mucus in the stool
- Have meningitis (inflammation of the meninges)
- Have a history of liver disease
- A history of abnormal heart rhythm

Stop use and ask a doctor if:
- Any undesirable effect occurs or if symptoms get worse
- Diarrhea lasts for more than 2 days
- Blood is present in stools
- Fever or abdominal swelling or bulging develops
- Constipation, abdominal distension, or ileus (blockage of the intestine) occurs

Dehydration 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 +632-8-**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: Aluminum Blister Foil x 4's and 10's (Box of 4's, 10's and 100's)
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