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

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