PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ADCO LOPERAMIDE, 2 mg tablets

Loperamide hydrochloride.

Contains sugar: Each tablet contains 43, 9 mg lactose.

Read all of this leaflet carefully because it contains important information for you.

ADCO LOPERAMIDE, 2 mg tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **ADCO LOPERAMIDE** tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ADCO LOPERAMIDE** tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2 days.

What is in this leaflet

1. What **ADCO LOPERAMIDE** tablets is and what it is used for.
2. What you need to know before you take **ADCO LOPERAMIDE** tablets.
3. How to take **ADCO LOPERAMIDE** tablets.
4. Possible side effects.
5. How to store **ADCO LOPERAMIDE** tablets.
6. Contents of the pack and other information.

1. What ADCO LOPERAMIDE tablets is and what it is used for:

ADCO LOPERAMIDE is an antidiarrhoeal medicine.

ADCO LOPERAMIDE inhibits gastrointestinal motility by effects on the circular and longitudinal muscles of the intestine. Part of its antidiarrhoeal effect may be due to a

reduction of gastro-intestinal secretion produced by actions at opioid receptors in the intestinal mucosa.

ADCO LOPERAMIDE tablets normalises the stool in both acute and chronic diarrhoea.

Children 2 to 5 years:

Loperamide is not indicated for acute and chronic nonspecific diarrhoea but for inhibition of peristalses and slowing of intestinal transit time.

Adults and children 6 years and older:

Loperamide is indicated for the symptomatic relief of acute and chronic nonspecific diarrhoea and to inhibit peristalsis and slow intestinal transit time in patients with ileostomies, colostomies and other intestinal resections.

2. What you need to know before you take ADCO LOPERAMIDE tablets

Do not take ADCO LOPERAMIDE tablets**:**

- If you are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of **ADCO LOPERAMIDE** tablets.
- Do not give **ADCO LOPERAMIDE** tablets to children under 2 years of age.
- If you have acute ulcerative colitis (colon lining inflammation).
- If you have diarrhoea associated with pseudomembranous colitis (colon inflammation due to increased bacteria) with the use of broad-spectrum antibiotics.
- If you have acute dysentery (intestinal infection), which is characterised by blood in diarrhoea and high fever.
- If you have bacterial enterocolitis (Inflammation of the digestive tract).
- **ADCO LOPERAMIDE** tablets should not be used when inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon and toxic megacolon (see Special warnings and precautions for use). **ADCO LOPERAMIDE** tablets must be discontinued promptly when constipation, abdominal distension or ileus develop.
- If you are lactose intolerant you should not take **ADCO LOPERAMIDE** tablets due to lactose content**.**
- The safety of use during pregnancy has not been established.

Warnings and precautions

Special care should be taken with **ADCO LOPERAMIDE** tablets:

- Treatment of diarrhoea with **ADCO LOPERAMIDE** tablets is only for symptomatic relief.
- If an underlying cause is known, specific treatment should be given.
- If you are suffering from any condition where constipation must be avoided.
- If you are suffering from liver problems.
- If you are suffering from inflammatory bowel (digestive system) disease. Observe for signs of inflammation or dilation of the colon.
- If you are experiencing diarrhoea, especially in infants, weakly and elderly people, fluid and electrolyte depletion may occur. If this happens, administer oral rehydration.
- Should not be used continuously for acute or chronic diarrhoea for children under 6 years and should not be given to children less than 6 years of age without supervision or medical prescription.
- Do not exceed the recommended dose and/or the recommended duration of treatment.
- If you are an AIDS patient treated with **ADCO LOPERAMIDE** tablets for diarrhoea. Therapy should be stopped once you see abdominal distention (bloating and swelling) in the belly area.
- In patients with hepatic dysfunction (liver problems).
- Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide.
- If symptoms persist for more than 2 days, consult a doctor.

Children and adolescents

Do not use in infants under two years of age.

ADCO LOPERAMIDE tablets is not recommended for routine use in acute and chronic diarrhoea in children under the age of 6 years and should not be given to children less than 6 years of age, without medical prescription and supervision.

Other medicines and ADCO LOPERAMIDE tablets:

- Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, **ADCO LOPERAMIDE** tablets can affect the following medicines:

- Ritonavir (used to treat HIV);
- Quinidine (used to treat abnormal heart rhythms or malaria);
- Itraconazole, ketoconazole (used to treat fungal infections);
- Gemfibrozil (used to reduce levels of cholesterol);
- Oral desmopressin (used to treat excessive urination).
- Other drugs that slow down or speed up movement in the gut.

Pregnancy, breastfeeding and fertility

The safety of this medicine in pregnant women has not yet been established.

If you are pregnant or think you are pregnant or planning a pregnancy, ask your doctor or pharmacist for advice before taking **ADCO LOPERAMIDE** tablets.

If you are breastfeeding do not take **ADCO LOPERAMIDE** tablets. Small amounts of **ADCO LOPERAMIDE** tablets may be found in breast milk. Ask your doctor or pharmacist for advice on appropriate treatment if you are breastfeeding.

The effect on human fertility has not been established.

Driving and using machines

ADCO LOPERAMIDE tablets may make you feel dizzy, drowsy and fatigued:

- Do not drive because **ADCO LOPERAMIDE** tablets could interfere with your ability to drive safely;
- Do not operate machinery or perform any tasks that require concentration, until you are certain that **ADCO LOPERAMIDE** tablets does not adversely affect your ability to do so.

ADCO LOPERAMIDE tablets contains lactose

If you are lactose intolerant, you should not take **ADCO LOPERAMIDE** tablets due to lactose content.

3. How to take ADCO LOPERAMIDE tablets

Do not share medicines prescribed for you with any other person.

Always take **ADCO LOPERAMIDE** tablets exactly as described in this leaflet or as your pharmacist, doctor or nurse has told you. You should check with your doctor or pharmacist or your nurse if you are unsure.

Dosage should not exceed four to six tablets per day.

For inhibition of peristalses and slowing of the intestinal transit time

For children 2 to 5 years: ½ a tablet eight hourly.

Acute diarrhoea

Adults: Two tablets initially, followed by one tablet after each loose stool.

Children of 6 years and older: One tablet initially, followed by one tablet after each loose stool.

The initial dose should be adjusted until solid stools are obtained.

Chronic diarrhoea

The dosage should be adjusted individually.

Adults: The initial dose is two tablets daily.

Children of 6 years and older: The initial dose is one tablet daily.

The initial dose should be adjusted until solid stools are obtained.

If constipation occurs, treatment should be stopped.

If you take more ADCO LOPERAMIDE tablets than you should:

Central nervous system (CNS) depression may occur:

- Stupor (A state where you are confused and nearly unconscious);
- Coordination (movement) abnormality;
- Somnolence (Sleepiness or feeling drowsy);
- Miosis (Uncontrolled constriction of the pupil of the eye);
- Muscular hypertonia (Decreased/Weak muscle tone);
- Respiratory depression (Slow and ineffective breathing);

- Urinary retention (Difficulty urinating);
- Constipation (When bowel movements become less frequent and stools become difficult to pass);
- Paralytic ileus (Intestinal blockage without physical obstruction).
- Excessive inhibition of peristalsis (movement of food from the throat to the intestines is restricted) with nausea and dryness of the mouth.

Children may be more sensitive to the central nervous system effects than adults.

Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ADCO LOPERAMIDE tablets

Do not take double dose to make up for forgotten individual doses.

4. Possible side effects

ADCO LOPERAMIDE tablets can have side effects.

Not all side effects reported for **ADCO LOPERAMIDE** tablets are included in this leaflet. Should your general health worsen or if you experience any unwanted effects while taking **ADCO LOPERAMIDE** tablets, please consult your health care provider for advice.

These are all serious side effects. If you have them, you may have had a serious reaction to **ADCO LOPERAMIDE** tablets. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Flatulence
- Nausea
- Constipation

Less frequent side effects:

- Dizziness
- Somnolence (Feeling sleepy)
- Loss of consciousness (Loss of alertness)
- Stupor (A state where you are confused and nearly unconscious)
- Depressed level of consciousness (alertness)
- Hypertonia (Muscle stiffness)
- Coordination abnormality (Problems with coordination)
- Miosis (Tiny pupils)
- Abdominal (stomach) discomfort
- Ileus, including paralytic ileus (Intestinal blockage without physical obstruction)
- Megacolon, including toxic megacolon (Abnormal expansion of the colon)
- Abdominal pain
- Dry mouth
- Rash
- Urinary retention (Difficulty urinating)
- Fatigue (Tiredness)

Frequency unknown:

- Hypersensitivity reaction (Allergy)
- Anaphylactic and Anaphylactoid reaction (Skin rash, nausea, vomiting, difficulty breathing and shock)
- Abdominal distension (Bloating and swelling in the belly area)
- Dyspepsia (Indigestion)
- Vomiting
- Bullous eruption (Fluid-filled blisters), including Stevens-Johnson syndrome
- Toxic epidermal necrolysis and erythema multiforme (Redness of the skin)
- Angioedema (Swelling underneath the skin)
- Inflammation of the pancreas (acute pancreatitis)
- Urticaria (Skin rash)
- Pruritus (Itchy skin)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **ADCO LOPERAMIDE** tablets.

Adverse reactions can also be reported to the Adcock Ingram Pharmacovigilance department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134

5. How to store ADCO LOPERAMIDE tablets:

Store in well-closed containers, at or below 25 ºC.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ADCO LOPERAMIDE tablets contain

The active substance is Loperamide Hydrochloride 2 mg per tablet.

Contains sugar: Lactose 43,9 mg.

The other ingredients are: gelatin, magnesium stearate, maize starch, purified water, sodium lauryl sulphate, sodium starch glycolate.

What ADCO LOPERAMIDE tablets looks like and contents of the pack:

White, round tablets

Cartons containing PVC/Aluminium foil blister strips of 6 white round tablets.

White cylindrical HDPE securitainers containing 60 and 300 white round tablets sealed with a LDPE screw cap.

Not all pack sizes may necessarily be marketed.

Holder of Certificate of Registration

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