PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

ADCO LOPERAMIDE 1 mg, syrup

Loperamide hydrochloride

Preservatives:

Methyl hydroxybenzoate	0,07 % *m/v*
Propyl hydroxybenzoate	0,008 % *m/v*

Contains sweetener:

Sodium saccharin	11, 58 mg

Sugar free

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

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

- Keep this leaflet, you may need to read it again.
- Do not share **ADCO LOPERAMIDE** syrup 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 48 hours.

Date of approval: 26 April 2023

What is in this leaflet?

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

1. What ADCO LOPERAMIDE syrup is and what it is used for

ADCO LOPERAMIDE syrup is a medicine acting on the gastrointestinal tract (digestive system) to stop or slow down diarrhoea.

Children 2 to 5 years:	Loperamide is not indicated for acute (short-lived) and chronic (long lasting) nonspecific diarrhoea (loose stools) but for slowing muscle movements of the bowel and for slowing the passing of food through the intestine.
Adults and children 6 years and older:	Loperamide is indicated for the symptomatic relief of acute (short-lived) and chronic (long lasting) nonspecific diarrhoea (loose stools) and to slowing muscle movements of the bowel and for slowing the passing of food through the intestine in patients with ileostomies, colostomies and other intestinal resections.

2. What you need to know before you take **ADCO LOPERAMIDE** syrup**.**

ADCO LOPERAMIDE syrup must be discontinued promptly when constipation, abdominal distension or ileus develop.

Do not take ADCO LOPERAMIDE syrup:

- If you are hypersensitive (allergic) to any of the other ingredients of **ADCO LOPERAMIDE** syrup (listed in section 6).
- As primary therapy in acute dysentery, which is characterised by blood in the stools and high fever.
- In children under 2 years of age.
- In patients with acute ulcerative colitis (colon lining inflammation).
- In patients with diarrhoea associated with pseudomembranous colitis (colon inflammation due to increased bacteria) and associated with the use of antibiotics.
- When slowing muscle movements of the bowel is to be avoided due to the possible risk of ileus (obstruction of the bowel), megacolon and toxic megacolon (abnormal expansion of the colon).
- In you have bacterial enterocolitis (Inflammation of the digestive tract) caused by bacteria.

Warnings and precautions

ADCO LOPERAMIDE syrup should be taken with care

- In conditions where constipation must be avoided.
- In patients with hepatic dysfunction (liver problems).
- In patients with inflammatory bowel disease.

- In patients with diarrhoea, especially in children, fluid and electrolyte depletion may occur. In such cases administration of appropriate fluid and electrolyte replacement is essential.
- In children under the age of 6 years. **ADCO LOPERAMIDE** syrup should not be given without a medical prescription and supervision. The product is not recommended for routine use in acute (sudden short-lived) or chronic (long-lasting) diarrhoea.
- If you are an AIDS patient treated with **ADCO LOPERAMIDE** syrup for diarrhoea. Therapy should be stopped at the earliest signs of abdominal distension (bloating and swelling) in the belly area.
- Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide.
- Do not take **ADCO LOPERAMIDE** syrup for prolonged periods. If you have persistent diarrhoea, this can be an indicator of potentially more serious conditions, consult the doctor for appropriate treatment.
- For acute (short-lived) diarrhoea, if symptoms persist for more than 2 days, consult a doctor.

Other medicines and ADCO LOPERAMIDE syrup

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

Please consult your doctor, pharmacist or other health care professional if you want to take **ADCO LOPERAMIDE** syrup but are taking 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, Breast-feeding and fertility

The safety in fertility, pregnancy and breastfeeding has not been established.

ADCO LOPERAMIDE syrup is not recommended during breastfeeding. Small amounts of loperamide may appear in the breast milk. Speak to your doctor, pharmacist or health care professional about suitable treatments.

If you are pregnant or breastfeeding your baby or think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other health care professional for advice before taking **ADCO LOPERAMIDE** syrup**.**

Driving and using machinery

ADCO LOPERAMIDE syrup may cause loss of consciousness or make you feel dizzy, drowsy, tired and lower your levels of consciousness (alertness). If you are affected do not operate machinery, drive or perform any tasks that may require your concentration.

3. How to take ADCO LOPERAMIDE syrup

Do not administer **ADCO LOPERAMIDE** syrup to infants under 2 years of age.

Always take **ADCO LOPERAMIDE** syrup exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Shake the bottle before use.

For inhibition of peristalses and slowing of the intestinal transit time

Children 2 to 5 years:	One medicine measureful (5 ml) per 12,5 kg body mass eight hourly.

***Acute diarrhoea*:**

Adults and children 6 years and older:	One medicine measureful (5 ml) per 12,5 kg body mass followed by ½ a medicine measureful (2,5 ml) per 12,5 kg after subsequent loose stool. Daily dosage should not exceed three medicine measuresful (15 ml)/12,5 kg body mass.

In acute (sudden short-lived) diarrhoea, if clinical improvement is not observed within 48 hours of administration of **ADCO LOPERAMIDE** syrup**,** this medication should be discontinued and a doctor should be consulted.

Chronic diarrhoea:

If constipation occurs, treatment should be discontinued.

Adults and children 6 years and older:	With individually adjusted dosage it is usually possible to obtain a virtually normal bowel movement. The initial dose is one medicine measureful (5 ml)/12,5 kg body mass daily for children. The initial dose should be adjusted until one to two solid stools per day are obtained. This is usually achieved on a maintenance dose of ½ to 2 medicine measuresful (2,5 ml to 10 ml) daily.

If you take more ADCO LOPERAMIDE syrup than you should

Symptoms of overdose may include:

- Depression of the central nervous system may present as follows:
    - 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).
- Children may be more sensitive to the central nervous system effects than adults.
- Excessive inhibition of peristalsis with nausea and dryness of the mouth.

- Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide.
- Convulsions have been reported in children under the age of two years.

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

4. Possible side effects

ADCO LOPERAMIDE syrup can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent

- Headache
- Dizziness
- Nausea
- Constipation
- Flatulence (wind)

Less Frequent

- Somnolence (feel sleepy)
- Abdominal(stomach) pain and discomfort

- Inflammation of the pancreas (acute pancreatitis)
- Vomiting
- Dyspepsia (indigestion)
- Rash
- Dry mouth

Frequency Unknown

- Hypersensitivity reaction (allergy),
- Anaphylactic and Anaphylactoid reaction (skin rash, nausea, vomiting, difficulty breathing and shock).
- Loss of consciousness and reduced level of consciousness(alertness)
- Stupor (A state where you are confused and nearly unconscious)
- Hypertonia and coordination abnormality (problems with co-ordination)
- Miosis (Tiny pupils)
- Ileus (Intestinal blockage without physical obstruction)
- Megacolon (abnormal expansion of the colon),
- Abdominal distension (Bloating and swelling in the belly area)
- Bullous eruption (fluid-filled blisters)
- Toxic epidermal necrolysis (life-threatening skin reaction).
- Erythema (Redness of the skin)
- Angioedema (swelling underneath the skin)
- Urticaria (skin rash)
- Pruritus (Itchy skin)
- Urinary retention(Difficulty urinating)
- Fatigue
- Fluid and electrolyte depletion

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 or nurse. 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** syrup.

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 syrup

- Store at or below 25 ºC and keep tightly closed.
- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **ADCO LOPERAMIDE** syrup contains:

Each 5 ml contains:

Loperamide hydrochloride 1 mg

Preservatives:

Methyl hydroxybenzoate	0,07 % *m/v*
Propyl hydroxybenzoate	0,008 % *m/v*
Contains sweetener:	
Sodium saccharin	11, 58 mg

The other ingredients are: Glycerin, Propylene glycol, Sodium saccharin, Red dye, Raspberry flavour, Citric acid monohydrate, Sodium hydroxide, Purified water.

What ADCO LOPERAMIDE syrup looks like and contents of the pack.

Clear, red syrup with a fruity raspberry flavour.

Round amber glass bottles containing 50 ml and 500 ml of syrup.

Not all pack sizes may necessarily be marketed.

Holder of Certificate of Registration

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