PATIENT INFORMATION LEAFLET FOR

CIPLA LOPERAMIDE

SCHEDULING STATUS S2

CIPLA LOPERAMIDE (2 mg, tablets).

Loperamide hydrochloride

Contains sugar: lactose monohydrate 100 mg per tablet.

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

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

- Keep this leaflet, you may need to read it again.
- Do not share CIPLA LOPERAMIDE 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.

WARNING: Serious heart problems, including abnormal heartbeat and death

- **Do not take more of CIPLA LOPERAMIDE than the recommended daily dose (see section 3), since CIPLA LOPERAMIDE may give rise to serious heart problems, including abnormal/irregular heartbeat (Torsades de Pointes) and cardiac arrest, which may be fatal (see "Take special care with CIPLA LOPERAMIDE" and "If you take more CIPLA LOPERAMIDE than you should").**
- **Do not give CIPLA LOPERAMIDE to children under 2 years of age (see "Do NOT take/give CIPLA LOPERAMIDE").**

What is in this leaflet

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

1. What CIPLA LOPERAMIDE is and what it is used for

CIPLA LOPERAMIDE (loperamide hydrochloride) belongs to a class of medicine known as antidiarrhoeals, medicines acting on gastrointestinal tract.

CIPLA LOPERAMIDE is used to treat diarrhoea (loose stools) in adults and children 6 years and older. It is used for:

- The symptomatic relief and control of acute (sudden onset and of short duration) diarrhoea and chronic (of longer duration or recurring) non-specific diarrhoea; and
- For slowing of intestinal transit time and peristalsis (slowing the movement of food through the bowels) in people with ileostomies, colostomies and other intestinal resections.

CIPLA LOPERAMIDE tablets is also taken by children younger than 6 years, who are able to swallow tablets, for slowing of intestinal transit time and peristalsis (slowing the movement of food through the bowels).

2. What you need to know before you take CIPLA LOPERAMIDE

Do not take/give CIPLA LOPERAMIDE:

- If you/your child are allergic (hypersensitive) to loperamide hydrochloride or to any of the inactive ingredients of CIPLA LOPERAMIDE.

- If your child is under the age of 2 years, as CIPLA LOPERAMIDE may cause difficulty breathing (respiratory depression) and serious heart problems (see **"Take special care with CIPLA LOPERAMIDE"**).
- If you/your child have stomach pain without diarrhoea (loose stools).
- If you/your child have any of the following, as you will require treatment by your doctor:
    - Severe watery diarrhoea/stools, which contains blood, mucus or pus and a high fever (acute dysentery).
    - Inflammation of the lining of the large intestine/colon causing you to have blood in the stools and rectal pain or bleeding (acute ulcerative colitis).
    - Pain, bleeding, or mucus-like discharge from the rectum which may be caused by bacteria (bacterial enterocolitis).
    - Inflammation of the large intestine/colon causing you to have diarrhoea that can be watery or bloody and may be associated with the use of antibiotics (pseudomembranous colitis).

Warnings and precautions

Take special care with CIPLA LOPERAMIDE:

Serious heart problems including abnormal heart rhythms and death

Do not take more of CIPLA LOPERAMIDE than the recommended daily dosage (see **section 3**), since CIPLA LOPERAMIDE may give rise to serious heart problems, including abnormal/irregular heartbeat and cardiac arrest, which may be fatal (see **"Abuse and misuse"** and **"If you take more CIPLA LOPERAMIDE than you should"**).

This risk may be further increased:

- By taking certain other medicines (such as amiodarone, quinidine, sotalol, erythromycin and certain antidepressants and antipsychotics, amongst others) (see **"Other medicines and CIPLA LOPERAMIDE"**).

- By taking herbal products that are known to affect the heart.
- A personal or family history of heart rhythm disorders.
- Electrolyte abnormalities / dehydration due to diarrhoea.
- In elderly people.

Please ask your doctor or pharmacist for advice if you are not sure.

You must immediately stop taking CIPLA LOPERAMIDE and report to your doctor if you, or your child, experiences fainting, a rapid or irregular heartbeat or becomes unresponsive.

Do not give CIPLA LOPERAMIDE to children younger than 2 years (see **"Do not take/give CIPLA LOPERAMIDE"**).

Dehydration / loss of fluid

Loss of fluids and electrolytes may occur in people with diarrhoea / loose stools, especially in young children and in frail and elderly people. In such cases, talk to your doctor or pharmacist about appropriate fluid and electrolyte replacement (oral rehydration therapy [ORT]), since it is very important to replace lost fluids and electrolytes. CIPLA LOPERAMIDE does not replace lost fluids or electrolytes.

Stomach / bowel disorders

You should not take CIPLA LOPERAMIDE if slowing of bowel movement could possibly increase your risk of bowel / intestinal obstruction. You must stop taking CIPLA LOPERAMIDE and report to your doctor immediately if swelling of the stomach, blood in the stools, fever, bowel / intestinal obstruction or constipation develops.

People with AIDS-associated diarrhoea / loose stools should stop taking CIPLA LOPERAMIDE and report to their doctor immediately if swelling of the stomach, blood in the stools, fever, bowel / intestinal obstruction or constipation develops.

CIPLA LOPERAMIDE treatment gives symptomatic relief of diarrhoea / loose stools only. You may require other treatment / medicine if an underlying cause of the diarrhoea is found, or if the diarrhoea does not stop. CIPLA LOPERAMIDE should not be used for prolonged periods, unless your doctor recommends it.

If improvement of acute (sudden onset) diarrhoea / loose stools does not occur within 48 hours, you should stop treatment with CIPLA LOPERAMIDE and consult your doctor.

Children

CIPLA LOPERAMIDE should not be given to children less than 6 years of age without a medical prescription and proper supervision by a doctor.

Do not give CIPLA LOPERAMIDE to children younger than 2 years due to the risk of difficult breathing (respiratory depression), fainting, and serious heart-related adverse reactions (see **"Do not take/give CIPLA LOPERAMIDE"**).

Children may be more sensitive to side effects, such as altered state of wakefulness, sleepiness and respiratory depression, than adults. There have been reports of obstruction of the bowel / intestine associated with swelling of the stomach.

The safety of CIPLA LOPERAMIDE in children with chronic (of longer duration or recurring) diarrhoea / loose stools has not been established.

In case of accidental overdose of CIPLA LOPERAMIDE by children, see **"If you take more CIPLA LOPERAMIDE than you should"**.

Allergic reactions

Report to your doctor immediately if you, or your child, experiences an allergic reaction, which may include swelling of the lips, face or tongue, skin rash, difficult breathing,

wheezing, hives, or itching may occur with CIPLA LOPERAMIDE (see **section 4**).

Liver function impairment

CIPLA LOPERAMIDE should be used with care in people with liver function impairment.

Kidney function impairment

Dosage adjustments in people with kidney function impairment is not required.

Elderly

Dosage adjustments in elderly people is not required. However, CIPLA LOPERAMIDE should be avoided in elderly people taking medicines that can result in irregular / abnormal heartbeat (e.g. people taking medicines to treat irregular heart rhythm) or in people with known risk factors for irregular heart rate.

Abuse and misuse

CIPLA LOPERAMIDE abuse and misuse have been reported. Do not take higher doses than that recommended, as CIPLA LOPERAMIDE can have suppressive effects on breathing at higher doses, or in combination with certain medicines (see **"Other medicines and CIPLA LOPERAMIDE"**).

Other medicines and CIPLA LOPERAMIDE

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

Please inform your doctor or pharmacist if you are taking any of the following medicines, as you may require special precautions:

- Medicines for the treatment of fungal infections, e.g. itraconazole, ketoconazole.
- Gemfibrozil, for treating raised cholesterol levels.

- Medicines to treat abnormal heart rhythms, e.g. quinidine, procainamide, amiodarone, sotalol (see **"Take special care with CIPLA LOPERAMIDE"**).
- Oral desmopressin, for treating excessive urination.
- Ritonavir or saquinavir, for treating HIV/AIDS.
- Medicines for the treatment of psychosis, e.g. chlorpromazine, haloperidol, thioridazine, ziprasidone.
- Moxifloxacin or pentamidine, used as antibiotics.
- Levomethadyl acetate or methadone, used to treat opioid addiction.
- Herbal products that are known to affect the heart.

CIPLA LOPERAMIDE with food, drink and alcohol

CIPLA LOPERAMIDE should be swallowed with a full glass of water and may be taken with or without meals.

Pregnancy, breastfeeding and fertility

Do not take CIPLA LOPERAMIDE while you are pregnant or breastfeeding your baby. CIPLA LOPERAMIDE may be present in breast milk.

Effect of CIPLA LOPERAMIDE on human fertility has not been evaluated.

If you are pregnant or breastfeeding, 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 CIPLA LOPERAMIDE.

Driving and using machines

CIPLA LOPERAMIDE may cause you to have varying levels of consciousness / alertness, or to feel tired, dizzy or drowsy and may therefore affect your ability to drive or operate

machinery (see **section 4**). Do not drive or operate machinery until you know how CIPLA LOPERAMIDE affects you.

CIPLA LOPERAMIDE contains

CIPLA LOPERAMIDE contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CIPLA LOPERAMIDE.

3. How to take CIPLA LOPERAMIDE

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

Always take CIPLA LOPERAMIDE exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

Do not give CIPLA LOPERAMIDE to children younger than 2 years. CIPLA LOPERAMIDE is in the form of tablets and therefore are not suitable for children under 6 years of age.

Acute (sudden onset and of short duration) non-specific diarrhoea / loose stools

Adults

Take 2 tablets (4 mg) initially, followed by 1 tablet (2 mg) after each subsequent loose stool.

Children 6 years and older

Take 1 tablet (2 mg) initially, followed by 1 tablet (2 mg) after each subsequent loose stool.

Do not exceed the following maximum daily doses:

Bodyweight (kg)	Maximum Daily Dose
14 to 19 kg	2 tablets (4 mg)
20 to 26 kg	3 tablets (6 mg)
27 to 33 kg	4 tablets (8 mg)

34 to 39 kg	5 tablets (10 mg)
40 to 46 kg	6 tablets (12 mg)
47 to 53 kg	7 tablets (14 mg)
≥ 54 kg	8 tablets (16 mg)

Important: STOP taking CIPLA LOPERAMIDE as soon as your diarrhoea is under control.

If you have acute (sudden onset) diarrhoea, that does not show improvement within 48 hours, you should stop taking CIPLA LOPERAMIDE and consult your doctor.

Chronic (of longer duration or recurring) non-specific diarrhoea (you must consult your doctor)

A normal bowel movement is usually obtained with individually adjusted dosages.

Initial dose

Adults: Take 2 tablets (4 mg) daily.

Children 6 years and older: Take 1 tablet (2 mg) daily.

The initial dose should be adjusted until 1 to 2 solid stools per day are obtained. This is normally achieved on a maintenance dose of 1 to 6 tablets (2 to 12 mg) per day.

You should decrease the dosage if constipation occurs.

Elderly:

No dose adjustment is necessary.

Elderly people may, however, be more susceptible to serious heart problems while taking CIPLA LOPERAMIDE. Therefore, you should not take CIPLA LOPERAMIDE if you are taking medicines for abnormal heart rhythms or have known risk factors for abnormal heart rhythms (see **"Take special care with CIPLA LOPERAMIDE"**).

Liver function impairment:

CIPLA LOPERAMIDE should be used with care in people with liver function impairment (see **"Take special care with CIPLA LOPERAMIDE"**). Please talk to your doctor or pharmacist if you are unsure.

If you have the impression that the effect of CIPLA LOPERAMIDE is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPLA LOPERAMIDE than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side effects listed below:

- Abnormal / irregular heartbeat, including fainting, that could be fatal.
- Altered state of wakefulness, sleepiness, or a state of unconsciousness.
- Difficult breathing (respiratory depression).
- Difficulty with coordination.
- Constriction of the pupil of the eye.
- Abnormal increase in muscle tension.
- Constipation, obstruction of the bowel / intestines, nausea and a dry mouth.
- Low blood pressure.
- Difficulty urinating.
- Seizures / convulsions in children younger than 2 years.

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

Do not exceed the daily dosing instructions. Higher than recommended CIPLA LOPERAMIDE doses may result in life-threatening heart problems including abnormal / irregular heartbeat, fainting, stopping of breathing and could be fatal.

If you have taken more of CIPLA LOPERAMIDE than you should, or if you experience fainting or abnormal heartbeat, stop taking CIPLA LOPERAMIDE and immediately report to your doctor or nearest hospital.

Children and people with liver function impairment seem to be more sensitive to the side effects of CIPLA LOPERAMIDE, including respiratory depression.

If you forget to take CIPLA LOPERAMIDE

Always take CIPLA LOPERAMIDE as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

CIPLA LOPERAMIDE can have side effects.

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

If any of the following happens, stop taking CIPLA LOPERAMIDE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, which may include a skin rash, fever, difficult breathing, wheezing, hives, itching, or swelling of the face, lips, or tongue (which may be life-threatening).
- Any skin rash with blister formation (which may be life-threatening).

These are all very serious side effects. If you have them, you may have had a serious reaction to CIPLA LOPERAMIDE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Those that occur less frequently:
    - Obstruction of the bowel (ileus or paralytic ileus), which may cause inability to have a bowel movement or pass gas, constipation, stomach pain, swelling / bloating of the stomach (abdominal distension), nausea and vomiting (see **"Take special care with CIPLA LOPERAMIDE"**).
    - Dilation of the large bowel / colon (megacolon, including toxic megacolon), which may cause painful bowel movement, blood in the stool, stomach pain, cramps, swelling / bloating of the stomach (abdominal distension) and fever (see **"Take special care with CIPLA LOPERAMIDE"**).
- Those that occur with unknown frequency:
    - Loss of consciousness, depressed level of consciousness, abnormal increase in muscle tension, difficulty with coordination.
    - Fast or irregular heartbeat (Torsades de Pointes or other ventricular dysrhythmias), prolonged QT interval on the electrocardiogram, chest pain, shortness of breath, fainting, light-headedness (cardiac arrest), and death (see **"Take special care with CIPLA LOPERAMIDE"** and **"If you take more CIPLA LOPERAMIDE than you should"**).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Constipation, flatulence (gas), nausea.

Less frequent side effects:

- Dizziness and drowsiness.
- Stomach pain or discomfort, dry mouth, vomiting, indigestion.

- Rash, hives and itching.

Side effects with unknown frequency:

- Sleepiness.
- Constriction of the pupil of the eye.
- Difficulty urinating (urinary retention).
- Tiredness, fatigue.
- Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis). If you get any of these, stop using CIPLA LOPERAMIDE and get medical help at once.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CIPLA LOPERAMIDE.

5. How to store CIPLA LOPERAMIDE

Store at or below 25 °C.

Protect from light and moisture.

Keep the blister strips in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the packaging material.

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 CIPLA LOPERAMIDE contains

The active substance is loperamide hydrochloride 2 mg per tablet.

The other ingredients are anhydrous colloidal silica, brilliant blue, lactose monohydrate, magnesium stearate, maize starch, polyvinyl pyrrolidone, quinoline yellow, sodium starch glycollate and talc.

What CIPLA LOPERAMIDE looks like and contents of the pack

Light green coloured, capsule shaped, biconvex, uncoated tablets, plain on one side and a break line on the other side.

CIPLA LOPERAMIDE is packed in an aluminium foil blister strips of 6 and 8 tablets packed in 6's, 8's and 12's (2 x 6's) in a carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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