

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS S2

#### LOPERASTAT<sup>®</sup> SYRUP

Loperamide hydrochloride

Preservatives:

Methylparaben	0,072 % <i>m/v</i>
Propylparaben	0,008 % <i>m/v</i>
Alcohol	1,4 % <i>v/v</i>

Sugar free, artificially sweetened.

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

LOPERASTAT<sup>®</sup> SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LOPERASTAT<sup>®</sup> SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOPERASTAT<sup>®</sup> 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.

What is in this leaflet

1. What LOPERASTAT SYRUP is and what it is used for
2. What you need to know before you take LOPERASTAT<sup>®</sup> SYRUP
3. How to take LOPERASTAT<sup>®</sup> SYRUP
4. Possible side effects
5. How to store LOPERASTAT<sup>®</sup> SYRUP
6. Contents of the pack and other information

## **1. What LOPERASTAT<sup>®</sup> SYRUP is and what it is used for**

LOPERASTAT<sup>®</sup> SYRUP is used to treat diarrhoea in adults and children 6 years and older. It contains loperamide hydrochloride, a substance that helps reduce diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by your body.

In children under the age of 6 years LOPERASTAT<sup>®</sup> SYRUP is used to slow down an overactive bowel. It should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor.

## **2. What you need to know before you take LOPERASTAT<sup>®</sup> SYRUP**

### **Do not take LOPERASTAT<sup>®</sup> SYRUP :**

- if you or your child are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of LOPERASTAT<sup>®</sup> SYRUP (listed in section 6);
- if you or your child have acute dysentery (symptoms may include blood in your stools and fever);
- if you have a flare-up of an inflammatory bowel condition like ulcerative colitis or if you have inflammation of your bowels caused by bacterial infections;
- if you or your child have severe diarrhoea after taking antibiotics;
- if you or your child are constipated, or your stomach appears swollen (especially in children with severe dehydration).

LOPERASTAT<sup>®</sup> SYRUP is contraindicated for use in children under the age of 2 years.

### **Warnings and precautions**

#### **Take special care with LOPERASTAT<sup>®</sup> SYRUP:**

- if you or your child have severe diarrhoea as your body loses more fluid, sugars and salts than normal. LOPERASTAT<sup>®</sup> SYRUP should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor;
- if you or your child have diarrhoea that lasts for more than 48 hours;

- if you or your child have acquired immunodeficiency syndrome (AIDS) and your stomach becomes swollen, stop taking LOPERASTAT® SYRUP immediately and contact your doctor;
- if you or your child suffer from any liver disease;
- if you have a history of substance abuse.

Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in LOPERASTAT® SYRUP.

### **Children and adolescents**

It should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor.

### **Other medicines and LOPERASTAT® SYRUP**

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

Tell your doctor or pharmacist if you or your child are currently using:

- quinidine (used to treat malaria);
- ritonavir (used to treat HIV/AIDS);
- itraconazole or ketoconazole (used to treat fungal infections);
- gemfibrozil (used to treat cholesterol (high levels of fat in your blood));
- desmopressin (used to control increased thirst and too much urination);
- any other medicines used to treat diarrhoea.

### **LOPERASTAT® SYRUP with food, drink and alcohol**

See section 3

### **Pregnancy, breast-feeding and fertility**

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 provider for advice before taking this medicine.

The safety of LOPERASTAT<sup>®</sup> SYRUP during pregnancy has not been established.

Small amounts of LOPERASTAT<sup>®</sup> SYRUP is excreted in breast milk.

### **Driving and using machines**

You may experience tiredness, dizziness or drowsiness if you suffer from diarrhoea and you are taking LOPERASTAT<sup>®</sup> SYRUP.

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how LOPERASTAT<sup>®</sup> SYRUP affects you.

### **LOPERASTAT<sup>®</sup> SYRUP contains**

- Glycerol which may cause headache, stomach upset and diarrhoea.
- Methylparahydroxybenzoate and propylparahydroxybenzoate may cause allergic reactions (possibly delayed).
- Small amounts of ethanol (alcohol), less than 100 mg per dose.

### **3. How to take LOPERASTAT<sup>®</sup> SYRUP**

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

Always take LOPERASTAT<sup>®</sup> SYRUP exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

**LOPERASTAT<sup>®</sup> SYRUP is contraindicated in children under the age of 2 years. The tablets are not suited for children under 6 years of age and should only be given to children under the age of 6 years under medical prescription or supervision.**

### **ACUTE NON SPECIFIC DIARRHOEA:**

One medicine measure (5 ml) per 12,5 kg body mass followed by half medicine measure (2,5 ml) per 12,5 kg after each subsequent loose stool.

Daily dosage should not exceed three medicine measures (15 ml) per 12,5 kg body mass.

<b>Weight in kilograms (kg)</b>	<b>Initial dose (ml)</b>	<b>On subsequent loose stools</b>	<b>Maximum daily dose</b>
10 - 14,9	5 ml	2,5 ml	15 ml
15 - 19,9	7,5 ml	*3,7 ml	20 ml
20	10 ml	5 ml	30 ml
40	15 ml	7,5 ml	60 ml
70	20 ml	10 ml	80 ml

\* 3, 7 ml is equal to 3/4 of a medicine measure.

**IMPORTANT:** Stop **LOPERASTAT® SYRUP** as soon as diarrhoea is under control.

**CHRONIC NON-SPECIFIC DIARRHOEA: (Consult your doctor)**

With individual adjusted dosage it is usually possible to obtain a virtually normal bowel movement.

Starting dose is 1 medicine measure (5 ml) per 12, 5 kg body mass a day for children.

The daily dose should be adjusted until 1-2 solid stools per day are obtained. This is usually achieved on a maintenance dose of ½ - 2 medicine measures (2,5 ml – 10 ml) daily.

If constipation occurs, the dosage should be decreased.

If you have the impression that the effect of **LOPERASTAT® SYRUP** is too strong or too weak, tell your doctor or pharmacist.

**If you take more LOPERASTAT® SYRUP than you should**

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

Take this leaflet and the rest of the remaining LOPERASTAT<sup>®</sup> SYRUP with you so the doctor will know what you have taken.

**If you forget to take LOPERASTAT<sup>®</sup> SYRUP**

You should only take LOPERASTAT<sup>®</sup> SYRUP as and when need it. If you forget to take a dose, take your next dose after your next loose stool.

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

**4. Possible side effects**

**LOPERASTAT<sup>®</sup> SYRUP can have side effects.**

Not all side effects reported for LOPERASTAT<sup>®</sup> SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOPERASTAT<sup>®</sup> SYRUP, please consult your health care provider for advice.

**If any of the following happens, stop taking LOPERASTAT<sup>®</sup> SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are a very serious side effects. If you have them, you may have had a serious allergic reaction to LOPERASTAT<sup>®</sup> SYRUP. 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:**

*Side effects occurring less frequently:*

- lack of bowel movements causing severe constipation;
- severe stomach pain or swelling;

- severe, painful skin rash causing blistering or peeling of the skin, also known as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme;
- difficulty urinating.

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;
- dizziness;
- constipation, flatulence (excessive wind), nausea (feeling sick).

Less frequent side effects

- dry mouth,
- vomiting (being sick),
- cramping or pain in your stomach area,
- swelling or discomfort of your stomach area, indigestion;
- drowsiness;
- abnormal coordination, stiffness (difficulty moving);
- reduced level of consciousness or loss of consciousness (passing out, feeling faint or less alert);
- constriction of your pupils;
- tiredness.
- 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).
- Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.

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 “**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 LOPERASTAT<sup>®</sup> SYRUP.

### **5. How to store LOPERASTAT<sup>®</sup> SYRUP**

Store at or below 25 °C. Protect from light.

Keep in the original container until required for use.

Do not refrigerate.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What LOPERASTAT<sup>®</sup> SYRUP contains**

Each 5 ml Syrup contains: Loperamide hydrochloride 1 mg

The other ingredients are ethanol 96 % v/v, glycerol, hydrochloric acid solution, methylparahydroxybenzoate, pineapple fruity flavour F379, propylparahydroxybenzoate, raspberry essence No.1, raspberry red powder, sodium cyclamate, sodium hydroxide solution.

**Applicant/PHCR:** Ranbaxy Pharmaceuticals (Pty) Ltd  
**Product proprietary name:** Loperastat Syrup

**Dosage form and strength:** Syrup and 1 mg per 5 ml

**What LOPERASTAT® SYRUP looks like and contents of the pack**

Clear, reddish-pink coloured syrup with a fruity flavour.

**Contents of the pack:**

Amber glass bottle containing 50 ml and 100 ml of the liquid.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext.1

Roodepoort, 1724

South Africa

**This leaflet was last revised in**

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**REGISTRATION NUMBER(S)**

28/11.9/0649 (S.A.)

**S2** BOT 0500757 (Botswana) (50 ml)

**NS1** 04/11.9/0996 (Namibia) (50 ml)