1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

GASTRON SYRUP 1 mg/5 ml

Loperamide hydrochloride

Contains sweetener: Saccharin sodium 12,50 mg

Sugar free

GASTRON TABLETS 2 mg

Loperamide hydrochloride

Contains sugar: Mannitol 80,0 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share GASTRON with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if you or your child's symptoms worsen or do not improve after 2 days.

What is in this leaflet

1. What GASTRON is and what it is used for
2. What you need to know before you take/give GASTRON

3. How to take/give GASTRON
4. Possible side effects
5. How to store GASTRON
6. Contents of the pack and other information

1. What GASTRON is and what it is used for

GASTRON belongs to a group of medicines called antidiarrhoeals. It contains loperamide hydrochloride, a medicine used to help 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.

2. What you need to know before you take/give GASTRON

Do not take/give GASTRON:

- if you or your child are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of GASTRON (listed in section 6),
- to children below 24 months of age (applicable to GASTON SYRUP),
- if you or your child have acute dysentery (symptoms may include blood in your stools and fever),
- if you or your child have swelling of the intestine lining (inflammatory bowel condition like ulcerative colitis) or if you have swelling (inflammation) of your bowel 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,
- if you or your child has acute diarrhoea due to an infection,
- if you or your child have liver problems, as this may lead to overdosing,
- if you are pregnant,
- to children younger than 5 years of age (applicable to GASTRON TABLETS).

You or your child should stop taking GASTRON if it becomes difficult to pass stools (constipation), your belly becomes swollen or bloated or if your or your child's intestine stops making those wave-like movements (ileus), with symptoms such as abdominal cramps, bloating, nausea, vomiting.

Warnings and precautions

Take special care with GASTRON:

- if you or your child have severe diarrhoea as your body loses more fluid, sugars and salts than normal. In such cases appropriate fluid and electrolyte replacement (oral rehydration therapy) should be given,
- if you or your child have diarrhoea that last longer than 48 hours, you should seek medical advice,
- if you or your child have acquired immunodeficiency syndrome (AIDS) and you or your child have trouble passing stools (constipation) and the stomach becomes swollen, stop taking GASTRON immediately and contact your doctor,
- if you or your child have a history of substance abuse,
- when taking or giving it for anything other than its intended use and never take or give more than the recommended amount. 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 GASTRON.

Children and adolescents

GASTRON TABLETS should not be given to children under 5 years of age.

GASTRON SYRUP should not be given to children under the age of 24 months.

Other medicines and GASTRON

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

Tell your doctor if you are taking any of the following:

- 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)), as concomitant use may increase the levels of loperamide, as contained in GASTRON,
- desmopressin (used to control increased thirst and too much urination), as concomitant use with GASTRON may increase the level of desmopressin in your blood,
- any other medicines used to treat diarrhoea, as this may influence the way that GASTRON works.

Pregnancy, breastfeeding and fertility

You should not take GASTRON if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking GASTRON.

Driving and using machines

You may experience fainting, tiredness, dizziness or drowsiness if you suffer from diarrhoea and you are taking GASTRON.

It is not always possible to predict to what extent GASTRON may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which GASTRON affects you (see section 4).

GASTRON SYRUP contains parahydroxybenzoates

Parahydroxybenzoates may cause delayed allergic reactions.

3. How to take/give GASTRON

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

Always take/give GASTRON exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

GASTRON TABLETS

Adults

Acute Diarrhoea

The usual starting dose of GASTRON TABLETS is two tablets (4 mg) followed by one tablet (2 mg) after each loose stool, up to a total of 8 tablets (16 mg) daily.

If there is no improvement within 48 hours, then stop administering GASTRON TABLETS and seek medical advice.

The following daily doses should not be exceeded:

WEIGHT IN KILOGRAMS (kg)	**MAXIMUM DAILY DOSE**
From 14 kg	2 tablets (4 mg)
From 20 kg	3 tablets (6 mg)
From 27 kg	4 tablets (8 mg)
From 34 kg	5 tablets (10 mg)
From 40 kg	6 tablets (12 mg)
From 47 kg	7 tablets (14 mg)
From 54 kg	8 tablets (16 mg)

Stop taking GASTRON TABLETS as soon as diarrhoea is under control.

Chronic Diarrhoea (consult your doctor)

The initial dosage is 2 to 4 tablets of GASTRON TABLETS daily in divided doses for adults. With individually adjusted dosage it is usually possible to achieve normal bowel movement. Should you struggle to pass stools (become constipated) then the dosage should be decreased.

GASTRON SYRUP

Acute Diarrhoea

If there is no improvement within 48 hours, then stop administering GASTRON SYRUP and seek medical advice.

CHILDREN 2 TO 5 YEARS (13 kg to 20 kg body mass)

The usual dose is one medicine measure (5 ml) of GASTRON SYRUP three times a day for the first day, followed by one medicine measure (5 ml) per 10,0 kg body mass after each loose stool.

CHILDREN 5 TO 8 YEARS (20 kg to 30 kg body mass)

The usual dose is one medicine measure (5 ml) of GASTRON SYRUP four times a day for the first day, followed by one medicine measure (5 ml) per 10,0 kg body mass after each loose stool.

The total daily dose should not exceed 4 medicines measures (20 ml).

CHILDREN 8 TO 12 YEARS (over 30 kg)

The usual dose is two medicine measures (10 ml) of GASTRON SYRUP three to four times a day, for the first day followed by one medicine measure (5 ml) per 10,0 kg body mass after each loose stool.

The total daily dose should not exceed 8 medicine measures (40 ml).

Chronic non-specific diarrhoea

With individual adjusted dosage it is usually possible to achieve normal bowel movement.

The 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 to 2 solid stools per day are obtained. This is usually achieved on a maintenance dose of half to 2 medicine measures (2,5 ml to 10 ml) daily.

If trouble passing stools (constipation) occurs, the dosage should be decreased.

If you take/give more GASTRON than you should

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

In the event of an overdose, you or your child may experience trouble passing stools (constipation), feeling sick (nausea), dryness of the mouth, sleepiness, difficulty breathing, difficulty passing urine, bloating and swelling of the stomach.

If you forget to take/give GASTRON

You should only give/take GASTRON as needed. If you forget to give/take a dose, give/take the next dose after the next loose stool.

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

4. Possible side effects

GASTRON can have side effects.

Not all side effects reported for GASTRON are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while taking/receiving GASTRON, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), erythema multiforme and toxic epidermal necrolysis (TEN).

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

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

- Poor balance, falling, difficulty walking, light-headedness (decreased level of consciousness),
- bloating and swelling around the belly area, fever and stomach pain (megacolon),
- pain in the stomach and back (pancreatitis),
- lack of bowel movements causing constipation, being unable to pass gas and feeling full (paralytic ileus),
- difficulty urinating and completely emptying the bladder (urinary retention).

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

Tell your doctor if you or your child notice any of the following:

Frequent side effects:

- Difficulty passing stools (constipation), dry mouth, flatulence (excessive wind, meteorism), cramping or pain in your stomach area, colic,
- nausea (feeling sick), vomiting (being sick),

- headache, feeling dizzy.

Less frequent side effects:

- Swelling or discomfort of your stomach area, indigestion, heartburn (hypertonia),
- abnormal coordination,
- pain or hot burning in the mouth (glossodynia),
- contraction of the pupil of the eye (miosis),
- tiredness (fatigue), sleepiness (somnolence), drowsiness.

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

Reporting of side effects

If you or your child get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of GASTRON.

5. How to store GASTRON

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 GASTRON TABLETS contain

The active ingredient is 2 mg of loperamide hydrochloride.

The other ingredients are magnesium stearate, mannitol, polyethylene glycol, starch maize, purified talc.

Contains sugar: Mannitol 80,0 mg

What GASTRON SYRUP contain

Each 5 ml of GASTRON SYRUP contains 1 mg of loperamide hydrochloride.

The other ingredients are colour Ponceau 4R red (C.I.16255), flavour raspberry, glycerol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, purified water, saccharin sodium, sodium hydroxide pellets (for pH adjustment).

Preservatives:

Methyl parahydroxybenzoate 0,072 % *m/v*

Propyl parahydroxybenzoate 0,008 % *m/v*

Contains sweetener: Saccharin sodium 12,50 mg

Sugar Free

What GASTRON TABLETS looks like and contents of the pack

GASTRON TABLETS is a flat, white, bevelled edged tablet bisected on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

6 or 300 tablets are packed in a clear polyvinylchloride blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

What GASTRON SYRUP looks like and contents of the pack

GASTRON SYRUP is a clear red liquid with a raspberry odour.

50 ml is packed into an amber polyvinylchloride bottle with a white, low density polyethylene snap cap.

50 ml is packed into an amber glass bottle with a black screw-cap, with an expanded polyethylene liner.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 (0)11 239-6200

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Registration numbers

GASTRON TABLETS: V/11.9/213

GASTRON SYRUP: V/11.9/214

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and

Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS1
GASTRON TABLETS: 04/11.9/0018
GASTRON SYRUP: 04/11.9/0017

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