1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DISCHEM ANTI-DIARRHOEAL TABLETS 2 mg

Loperamide hydrochloride

Contains sugar: Mannitol 80 mg

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

DISCHEM ANTI-DIARRHOEAL TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take DISCHEM ANTI-DIARRHOEAL TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DISCHEM ANTI-DIARRHOEAL TABLETS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- In acute diarrhoea, if your symptoms worsen or do not improve within 48 hours then you must see a doctor.

What is in this leaflet

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

1. What DISCHEM ANTI-DIARRHOEAL TABLETS is and what it is used for

DISCHEM ANTI-DIARRHOEAL TABLETS belongs to a group of medicines called antidiarrhoeals.

DISCHEM ANTI-DIARRHOEAL TABLETS are used to treat the symptoms of acute and chronic diarrhoea in adults and children older than 6 years of age.

This medicine contains loperamide hydrochloride, 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.

2. What you need to know before you take DISCHEM ANTI-DIARRHOEAL TABLETS

Do not take DISCHEM ANTI-DIARRHOEAL TABLETS:

- if you or your child are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of DISCHEM ANTI-DIARRHOEAL TABLETS (listed in section 6 below),
- if you or your child have dysentery (symptoms may include blood in your stools and fever),
- if you or your child has acute diarrhoea due to an infection,
- 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 have liver problems, as this may lead to overdosing,
- if you or your child must avoid inhibition of movement of the muscles of bowel (peristalsis), due to the possible risk of significant sequelae including obstruction of the intestines (ileus), bloating and swelling around the belly area and stomach pain (megacolon) and toxic megacolon,
- if you or your child have trouble passing stools (constipated),

- if you are pregnant,
- if your child is under the age of 6 years.

You or your child should stop taking DISCHEM ANTI-DIARRHOEAL TABLETS 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 DISCHEM ANTI-DIARRHOEAL TABLETS:

- if you or your child have severe diarrhoea as your body loses more fluid, sugars and salts than normal,
- if you or your child have diarrhoea that lasts for more than 48 hours then please consult your doctor,
- if you or your child have acquired immunodeficiency syndrome (AIDS) and your stomach becomes swollen, stop taking DISCHEM ANTI-DIARRHOEAL TABLETS immediately and contact your doctor,
- if you or your child has a lack of bowel movement (constipation), swollen abdomen (abdominal distention), partial obstruction of the intestinal lumen (subileus), as DISCHEM ANTI-DIARRHOEAL TABLETS should be discontinued if this occurs,
- if you or your child suffer from serious heart problems (QT interval and QRS complex prolongation),
- if you or your child have a history of substance abuse.

Do not take more medicine than the recommended amount and/or for longer than recommended. Heart problems (Brugada syndrome symptoms including irregular heartbeat)

have been reported in patients who have taken too much loperamide, the active ingredient in DISCHEM ANTI-DIARRHOEAL TABLETS.

Children

DISCHEM ANTI-DIARHOEAL TABLETS is not suitable for use in children under 6 years of age.

Other medicines and DISCHEM ANTI-DIARRHOEAL TABLETS

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

Tell your doctor or pharmacist 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 DISCHEM ANTI-DIARRHOEAL TABLETS,
- desmopressin (used to control increased thirst and too much urination), as concomitant use with DISCHEM ANTI-DIARRHOEAL TABLETS may increase the level of desmopressin in your blood,
- any other medicines used to treat diarrhoea, as this may influence the way that DISCHEM ANTI-DIARRHOEAL TABLETS work.

Pregnancy, breastfeeding and fertility

You should not take DISCHEM ANTI-DIARRHOEAL TABLETS 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 this medicine.

Driving and using machines

You may experience fainting, tiredness, dizziness or drowsiness if you suffer from diarrhoea, and you are taking DISCHEM ANTI-DIARRHOEAL TABLETS.

It is not always possible to predict to what extent DISCHEM ANTI-DIARRHOEAL TABLETS 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 DISCHEM ANTI-DIARRHOEAL TABLETS affects you (see section 4).

3. How to take DISCHEM ANTI-DIARRHOEAL TABLETS

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

Always take DISCHEM ANTI-DIARRHOEAL TABLETS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Short-term diarrhoea:

Adults and children 6 years and older:

The usual dose is 2 tablets for adults, or one tablet for children as an initial dose (starting dose), followed by 1 tablet after each loose stool.

If your diarrhoea does not improve within 48 hours, you must stop treatment and contact your doctor.

Do not exceed the following maximum daily dosages:

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)

It is important that you stop taking DISCHEM ANT-DIARRHOEAL TABLETS as soon as the diarrhoea is under control.

Long-term diarrhoea: (consult with your doctor)

Adults and children over 6:

The initial dose is 2 tablets (4 mg) daily for adults and 1 tablet (2 mg) daily for children of 6 years and over.

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

If constipation occurs, the dosage should be decreased.

If you take more DISCHEM ANTI-DIARRHOEAL TABLETS than you should

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

Overdosage may result in convulsions, dizziness, fainting (Brugada syndrome), irregular heartbeats (dysrhythmia) and lack of bowel movement (constipation).

If you forget to take DISCHEM ANTI-DIARRHOEAL TABLETS

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

If you have missed a dose of DISCHEM ANTI-DIARRHOEAL TABLETS, take your next dose after your next loose stool.

4. Possible side effects

DISCHEM ANTI-DIARRHOEAL TABLETS can have side effects.

Not all side effects reported for DISCHEM ANTI-DIARRHOEAL TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DISCHEM ANTI-DIARRHOEAL TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking DISCHEM ANTI-DIARRHOEAL TABLETS 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 have them, you may have had a serious reaction to DISCHEM ANTI-DIARRHOEAL TABLETS. 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:

- poor balance, falling, difficulty walking, light-headedness (decreased level/loss of consciousness, stupor),
- bloating and swelling around the belly area and stomach pain (megacolon, including toxic 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.

These are all serious side effects. If you have them, you may have had a serious reaction to DISCHEM ANTI-DIARRHOEAL TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you 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 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 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

By reporting side effects, you can help provide more information on the safety of DISCHEM ANTI-DIARRHOEAL TABLETS.

5. How to store DISCHEM ANTI-DIARRHOEAL TABLETS

Store all medicines out of reach of children.

Store at or below 25 ºC.

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 DISCHEM ANTI-DIARRHOEAL TABLETS contains

The active substance is 2 mg of loperamide hydrochloride.

The other ingredients are macrogol, magnesium stearate, mannitol, starch (maize), and talc (purified).

Contains sugar: Mannitol 80 mg

What DISCHEM ANTI-DIARRHOEAL TABLETS looks like and contents of the pack

DISCHEM ANTI-DIARRHOEAL 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.

DISCHEM ANTI-DIARRHOEAL TABLETS is available in polyvinylchloride/aluminium foil blister packs of 6 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

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