SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ADCO-PRODIUM (TABLET)

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

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

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

1. WHAT ADCO-PRODIUM CONTAINS

The active substance is Loperamide hydrochloride 2 mg per each tablet

Nipastat/Salistat (total parabens) 0,13 % *m/m*

Sugar free

The other ingredients are Collodial silicon dioxide, Magnesium Stearate, Microcrystalline cellulose, Pregelatinised starch.

2. WHAT ADCO-PRODIUM IS USED FOR

ADCO-PRODIUM belongs to a group of medicines called 'Antidiarrhoeals' which reduces diarrhoea by slowing down the movement of the intestine

ADCO-PRODIUM also help the body to absorb more water and salts from the bowel.

ADCO-PRODIUM are used to treat short –lived (Acute) and long lasting (chronic) cases of diarrhoea in adult and children over 6 year old and older.

3. BEFORE YOU TAKE ADCO-PRODIUM

Do not take ADCO-PRODIUM:

- If you are hypersensitive (allergic) to Loperamide or any of the other ingredients of **ADCO-PRODIUM**.
- If inhibition of peristalsis must be avoided (e.g. partial obstruction due to tumour).
- If you have a liver problem or disease.
- Do not use in infants under two years of age.

Special care should be taken with ADCO-PRODIUM:

- if you have impaired liver function
- when an excess amount of **ADCO-PRODIUM** is taken, it may cause severe liver damage
- If patients with inflammatory bowel disease receiving **ADCO**-**PRODIUM** should be carefully observed for signs of toxic megacolon (large intestine widening).
- When you have diarrhoea, your body loses large amounts of fluid and salts. You should therefore replace this lost fluid by drinking more than normal amounts of fluids/liquid. This is especially important for children.
- **ADCO-PRODIUM** is not recommended for routine use in short –lived (Acute) and long lasting (chronic) diarrhoea in children under the age of 6 years.
- **ADCO-PRODIUM** should not be given to children less than 6 years of age, without medical prescription and supervision.
- If constipation occurs, treatment should be discontinued.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

ADCO-PRODIUM may make you feel dizzy and with fatigue

- Do not drive because **ADCO-PRODIUM** could interfere with your ability to drive safely
- Do not operate any tools or machines

Taking other medicines with ADCO-PRODIUM:

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

4. HOW TO TAKE ADCO-PRODIUM

Do not share medicines prescribed for you with any other person

Always take **ADCO-PRODIUM** exactly as your doctor has instructed you. You should check with your doctor or at pharmacist if you are unsure.

The usual dose is:

For short –lived (Acute) diarrhoea:

For adults and children of 6 years and older: 2 tablets (adults) or 1 tablet (children) as an initial dose followed by 1 tablet after each subsequent loose stool. Dosage should not exceed 8 tablets per day for adults or, depending on age, 4 to 6 tablets per day for children.

For long lasting (chronic) non-specific diarrhoea:

For adults and children of 6 years of age and older: With individually adjusted dosage it is usually possible to obtain a virtually normal bowel movement. The initial dose is 2

tablets daily for adults and 1 tablet daily for children of 6 years and over. The initial 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 daily. If constipation occurs, treatment should be discontinued.

For children 2 to 5 years old:

ADCO-PRODIUM is not indicated for acute and chronic non-specific diarrhoea but inhibition of peristalsis and slowing of intestinal transit time.

Dosage: Half a tablet eight hourly.

If you take ADCO-PRODIUM more than you should:

If constipation occurs, treatment should be discontinued

Treatment is symptomatic and supportive

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

If you forget to take or missed a dose of ADCO-PRODIUM:

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

5. POSSIBLE SIDE EFFECTS

ADCO-PRODIUM can have side effects.

Not all side effects reported for **ADCO-PRODIUM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Tell your doctor if you notice any of the following:

Abdominal pain

gastrointestinal disturbances including toxic megacolon (widening of the large intestine),

dry mouth,

dizziness,

fatigue

skin rashes.

6. STORING AND DISPOSING OF ADCO-PRODIUM

Store in well-closed containers at or below 30 °C.

Store all medicines out of reach of children.

Do not store in bathrooms.

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

Do not use **ADCO-PRODIUM** if you notice any visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF ADCO-PRODIUM

10’s and 500’s tablets packed in white, polypropylene securitainers.

500's tablets packed in a white, cylindrical screw type HDPE container with HDPE cap and induction seal.

8. IDENTIFICATION OF ADCO-PRODIUM

Round, white, normal convex, bisected tablet, 6,35 mm in diameter.

9. REGISTRATION NUMBER

X/11.9/303

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION :

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

11. DATE OF PUBLICATION OF THIS PACKAGE INSERT

07 March 1991