Patient Information Leaflet for Medicines for Human Use:
PECTIKON Suspension

SCHEDULING STATUS: S0

PECTIKON Suspension

Light kaolin and apple pectin

Preservatives:

Methylparaben 0,2 % *m/v*

Propylparaben 0,1 % *m/v*

Alcohol content:

Benzyl alcohol 0,1 % *v/v*

Ethanol 0,57 % *v/v*

Contains sugar:

Sorbitol 840 mg per 30 mL

Contains sweeteners:

Saccharin sodium 7,2 mg per 30 mL

Sodium cyclamate 60 mg per 30 mL

Contains TARTRAZINE.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PECTIKON with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 48 hours.

What is in this leaflet

1. What PECTIKON is and what it is used for

PECTIKON contains kaolin (a naturally occurring, soft, white clay mineral) and apple pectin (a soluble fibre and a type of carbohydrate, naturally found in apples and used as a gelling agent). The kaolin and pectin in PECTIKON exhibit intestinal adsorbent properties and forms a soothing film when put onto the surface of the gastrointestinal membrane (due to demulcent properties) which is meant to relieve the irritation of the inflamed gastrointestinal membrane.

PECTIKON is used as an extra treatment to rest, fluids and an appropriate diet in the treatment of the symptoms of mild to moderate diarrhoea not caused by an infection, which can stem from various factors like food intolerances, medication side effects, or underlying gastrointestinal conditions.

2. What you need to know before taking PECTIKON

Do not take PECTIKON:

- If you are hypersensitive (allergic) to kaolin and apple pectin, or to any of the other ingredients of PECTIKON (listed in section 6).
- If you have a condition where something blocks the normal passage of food, liquid, and waste through the intestines, either partially or completely(intestinal or bowl obstruction).
- If you have a common digestive disorder characterised by abdominal pain, bloating, and changes in bowel habits like diarrhoea or constipation (spastic bowel or spastic colon).

Warnings and precautions

Take special care with PECTIKON:

- Children: As diarrhoea can cause fluid and salt loss from the body, a severe and life threatening condition can arise (severe dehydration). Therefore, in children under 3 years of age PECTICON must not be used and a doctor should be consulted if the child is having diarrhoea (the passage of 3 or more loose or liquid stools per day or more frequent passage than is normal for the individual). In children 3 years and older, antidiarrhoeal medicine, such as PECTICON, can be given, but you must ensure that adequate amounts of fluid and electrolytes (salts and minerals in the blood and other body fluids that carry an electric charge) are taken by the child to replenish the fluid and electrolyte loss by the body due to the diarrhoea. If at any time you are unsure, please contact your doctor, pharmacist or healthcare provider for further advice.
- Adults: In older adults the loss of fluid and electrolytes due to diarrhoea can be very severe, and in addition to using an antidiarrhoeal medicine, such as PECTIKON, the patient should also maintain an adequate fluid and electrolyte intake.
- If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- If you have infectious diarrhoea, which can be caused by a variety of bacterial, viral and parasitic organisms (e.g. dysentery), you should not use PECTIKON as your condition may

get worse. A different kind of treatment may be needed. Make sure you tell your doctor, pharmacist or healthcare provider of these problems, so they can advise you on what to do.

- If your or your child's symptoms worsen or do not improve after 48 hours, you must see a doctor.

Other medicines and PECTIKON

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

- The active ingredients in PECTIKON can prevent the absorption of some medicines from your gut to make their effect weaker. If you are unsure, please speak to your pharmacist about this.
    - Lovastatin is a medicine used to treat high blood cholesterol and reduce the risk of cardiovascular disease. You should not take these medicines at the same time that you take PECTIKON.

PECTIKON with food, drink and alcohol

You should avoid drinking alcohol during treatment with PECTIKON.

Pregnancy and breastfeeding

You should not receive PECTIKON while you are pregnant or breastfeeding your baby as the safety of PECTIKON during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while receiving PECTIKON, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Driving and using machines

PEKTIKON should have no or negligible influence on the ability to drive and use machines. Do not drive or operate machinery until you are aware of the measure to which PECTIKON affects you.

Excipient warnings

PECTIKON contains tartrazine

PECTIKON contains tartrazine (FD & C Yellow No 5), which may cause allergic-type reactions (including inflammation, narrowing and swelling of the airways, leading to difficulty breathing, wheezing, coughing, and chest tightness). You may be more likely to develop an allergic reaction from tartrazine if you are also allergic to aspirin.

PECTIKON contains sorbitol

This medicine contains 140 mg sorbitol in each 5 mL suspension.
Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

PECTIKON contains alcohol

This medicine contains 22,8 mg of alcohol (ethanol) in each 5 mL of suspension. The amount in 5 mL of this medicine is equivalent to less than 12 mL beer or 5 mL wine. The small amount of alcohol in this medicine is not likely to have an effect on adults and adolescents, and its effect in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

3. How to take PECTIKON

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

General information

If the symptoms continue for longer than 2 days (48 hours) or if your condition gets worse, do not continue to take PECTIKON, and consult your doctor immediately.

It is important to remember to replace the fluid lost by the body and to maintain an adequate diet in addition to taking this medicine. During the first 24 hours you should drink plenty of clear liquids and during the next 24 hours you may eat bland food such as cooked cereals, bread or crackers. Until your condition improves, avoid fruits, vegetables, fried or spicy foods, bran, candy, caffeine or alcoholic beverages as these may worsen your condition.

If you do not drink enough liquid to replace the fluid you are losing while you have the diarrhoea, a serious condition may arise. Check with your doctor immediately if any of the following symptoms occur: a decreased passing of urine, dizziness or lightheadedness, dryness of the mouth, an increased thirst or a wrinkled skin.

The usual dose is:

For adults

3 to 6 medicine measures (15 mL to 30 mL) three to four times a day.

For children

12 years and over

3 to 6 medicine measures (15 mL to 30 mL) three to four times a day.

6 to 12 years old

2,5 to 5 medicine measures (12,5 mL to 25 mL) three to four times a day.

3 to 6 years old

1 to 2,5 medicine measures (5 mL to 12,5 mL) three to four times a day.

PECTIKON must be taken orally. REMEMBER TO SHAKE THE BOTTLE BEFORE USING THE MEDICINE.

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

If you take more PECTIKON 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.

If you forget to take PECTIKON

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

4. Possible side effects

PECTIKON can have side effects.

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

If any of the following happens, stop taking/using PEKTIKON 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.

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

Tell your doctor if you notice any of the following:

Side effects occurring with frequency unknown

- Infrequent or difficult bowel movements, often resulting in hard, dry stools that are painful to pass (constipation)
- an increase in the amount of air/gas in the stomach (flatulence),
- swelling of the stomach (distension),
- a partial or complete blockage of the small or large intestine that prevents the normal passage of food, liquid, gas, and stool (bowel/intestinal obstruction).

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

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

5. How to store PECTIKON

Store all medicines out of reach of children.

- Store in a cool place at or below 25 °C.
- Protect from light.
- Do not use after the expiry date stated on the bottle label/unit and carton.

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 PECTIKON contains

- The active substances are kaolin and pectin.
- The other ingredients are:

  Banana essence

  Benzyl alcohol

  Chloroform

  Methyl hydroxybenzoate

  Propyl hydroxybenzoate

  Saccharin sodium

  Sodium cyclamate

  Sorbitol

  Spirit chloroform

  Water

  Xanthan gum

  Yellow Tartrazine (FD & C Yellow No 5) (H706l) CI19140.

What PECTIKON looks like and contents of the pack

PECTIKON is a yellow suspension with an odour and taste of banana and is presented in amber HDPE containers containing 100 mL, 200 mL or 2,5 L.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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4300

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