Professional Information for Medicines for Human Use:
PECTIKON Suspension

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

PECTIKON Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 30 mL contains:

Light kaolin 6 g

Apple pectin 450 mg

Preservatives:

Methylparaben 0,2 % *m/v*

Propylparaben 0,1 % *m/v*

Alcohol content:

Benzyl alcohol 0,1 % *v/v*

Ethanol 0,51 % *v/v*

Contains sugar:

Sorbitol 1,56 g per 30 mL

Contains sweeteners:

Saccharin sodium 7,2 mg per 30 mL

Sodium cyclamate 60 mg per 30 mL

Contains TARTRAZINE.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

A yellow suspension with an odour and taste of banana.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As an adjunct to rest, fluids and appropriate diet in the symptomatic (relating to symptoms) treatment of mild to moderate acute non-infective diarrhoea.

4.2 Posology and method of administration

Posology

General information

If the symptoms persist for longer than 48 hours or the condition of the patient deteriorates, the product must be discontinued and a doctor consulted. In the treatment of diarrhoea, it is important that hydration be maintained by administering adequate fluids and electrolytes.

Adults

15 mL to 30 mL three to four times daily.

Children

12 years and over

15 mL to 30 mL three to four times daily.

6 to 12 years

12,5 mL to 25 mL three to four times daily.

3 to 6 years

5 mL to 12,5 mL three to four times daily.

Method of administration

PECTIKON suspension is for oral administration.

SHAKE THE BOTTLE BEFORE USE.

4.3 Contraindications

- Hypersensitivity to the active substances or any excipients listed in section 6.1.
- Patients with intestinal obstruction and patients with spastic bowel conditions.

4.4 Special warnings and precautions for use

Alcohol

The concomitant use of alcohol should be avoided.

Medicine absorption

The adsorbent properties of kaolin, as in PECTIKON may reduce the gastrointestinal absorption of other medicines (see section 4.5).

Gastrointestinal disorders

Pectin, as in PECTIKON should not be given to patients with intestinal obstruction (see section 4,8).

Excipients

Tartrazine

PECTIKON contains tartrazine (FD & C Yellow No 5), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity.

Sorbitol

This medicine contains 140 mg sorbitol in each 5 mL suspension.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given PECTIKON.

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 drowsiness.

4.5 Interaction with other medicines and other forms of interaction

Reduced gastrointestinal absorption

Pectin, as in PECTIKON may lower the transit time through the gut and may affect the absorption of other medicines when administered concomitantly.

Pectin, used with a lipid-lowering diet and lovastatin, a lipid regulating medicine, has resulted in a paradoxical increase in low-density lipoprotein (LDL)-cholesterol in patients with hypercholesterolaemia. It was believed the pectin reduced the absorption of lovastatin from the gut.

Kaolin, as in PECTIKON, can form insoluble complexes with some medicines in the gastrointestinal tract and reduce their absorption resulting in a reduced serum concentration and potentially a decrease in efficacy (see section 4.4); oral doses should not be taken at the same time as PECTIKON.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of PECTIKON in pregnancy has not been established.

Breastfeeding

The safety of PECTIKON in lactation has not been established.

4.7 Effects on ability to drive and use machines

The active ingredients in PECTIKON are not absorbed into the body and should have no or negligible influence on the ability to drive and use machines (see sections 4.4 and 4.8).

4.8 Undesirable effects

a. Summary of the safety profile

Constipation may occur.

Pectin, as in PECTIKON may temporarily increase flatulence and distension, and intestinal obstruction has been reported after administration (see section 4.4).

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Gastrointestinal disorders	Frequency unknown	Constipation, flatulence, distension, intestinal obstruction (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

4.9 Overdose

Symptoms and signs

Gastrointestinal symptoms such as constipation and intestinal obstruction may be evident (see section 4.8).

Treatment

Gastrointestinal symptoms may be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 11.9 Antidiarrhoeals

Mechanism of action

The kaolin and pectin in PECTIKON exhibit intestinal adsorbent and demulcent properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store in a cool place at or below 25 ºC. Protect from light.

6.5 Nature and contents of container

PECTIKON is stored in amber HDPE containers containing 100 mL, 200 mL or 2,5 L.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Gulf Drug Company (Pty) Ltd

22 Burnside Drive

Old Mill Industrial Park

Mount Edgecombe

4300

8. REGISTRATION NUMBER

E1413 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

28 October 2025