SCHEDULING STATUS S0

1. NAME OF THE MEDICINE

PECTIN-K SUSPENSION 3,0 g/0,220 g per 15 ml suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Kaolin (light)		3,0 g
Apple Pectin		0,220 g
Preservatives:	Methyl hydroxybenzoate	0,1 % *m/v*
	Propyl hydroxybenzoate	0,02 % *m/v*

Contains sweetener: Sodium saccharin 15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

A white to yellowish-white suspension with a butterscotch flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of non-infective diarrhoea.

4.2 Posology and method of administration

Posology

Shake the bottle before use.

Children 3 years and older:

One to three 5 ml medicine measures (5 ml to 15 ml) every three to four hours.

Adults:

Three to six 5 ml medicine measures (15 ml to 30 ml) every three to four hours.

It is recommended that PECTIN-K SUSPENSION is taken at least 2 to 3 hours before or after other oral medicines (see section 4.5).

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.

Method of administration

For oral administration.

4.3 Contraindications

- Hypersensitivity to kaolin, pectin or to any of the excipients listed in section 6.1.
- Intestinal obstruction. Patients with chronic ulceration of the gastro-intestinal tract or who have undergone colostomies.
- Spastic bowel conditions.
- Diarrhoea accompanied by fever or by blood or mucus in the stool.

4.4 Special warnings and precautions for use

In the treatment of diarrhoea it is important that hydration be maintained by administering adequate fluids and electrolytes.

PECTIN-K SUSPENSION contains sodium

PECTIN-K SUSPENSION contains 91,43 mg sodium per 15 ml, equivalent to 4,57 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

The elderly

Caution is recommended when used by the elderly because of the risk of fluid and electrolyte loss.

Paediatric population

The use of PECTIN-K SUSPENSION is not recommended in infants and children up to 3 years of age unless directed by a doctor.

4.5 Interaction with other medicines and other forms of interaction

The adsorbent properties of kaolin may influence the gastro-intestinal absorption of other medicines.

Concurrent use of PECTIN-K SUSPENSION with anticholinergics or medicines with anticholinergic activity, antidyskinetics, digitalis glycosides, lincomycins, loxapine, phenothiazines or thioxanthenes may impair absorption of these medicines when administered orally which can result in decreased therapeutic effectiveness. It is recommended that PECTIN-K SUSPENSION is administered at least 2 to 3 hours before or after other oral medicines.

The concomitant use of alcohol should be avoided.

4.6 Fertility, pregnancy and lactation

The safety of PECTIN-K SUSPENSION in pregnancy and lactation has not been established.

There is no information on the effect of PECTIN-K SUSPENSION on fertility.

4.7 Effects on ability to drive and use machines

PECTIN-K SUSPENSION has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Gastrointestinal disorders

Frequency unknown: Constipation. This side effect is usually mild and transient, but may less frequently lead to faecal impaction. Pectin may temporarily increase flatulence and distension, and intestinal obstruction has been reported after administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of PECTIN-K SUSPENSION is important. It allows continued monitoring of the benefit/risk balance of PECTIN-K SUSPENSION. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA online: https://www.sahpra.org.za/Publications/Index/8**.**

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A11.9 Antidiarrhoeals.

Pharmacotherapeutic group: Other intestinal adsorbents.

ATC code: A07BC01 and A07BC02

Mechanism of action

PECTIN-K SUSPENSION exhibits intestinal adsorbent and demulcent properties. Adsorbent and protectant. Kaolin is a natural hydrated aluminium silicate that is believed to adsorb large numbers of bacteria and toxins and reduce water loss. Pectin is a polyuronic polymer for which the mechanism of action is unknown. Pectin consists of purified carbohydrate extracted from citrus fruit or apple pomace. Studies have shown no decrease in stool frequency or faecal weight and water content with this combination even though stools appeared more formed.

5.2 Pharmacokinetic properties

Absorption

Not absorbed (up to 90 % of pectin is decomposed in the gastrointestinal tract).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium

Methyl hydroxybenzoate

Propyl hydroxybenzoate

Propylene glycol

Purified water

Sodium hydroxide (for pH-adjustment)

Sodium saccharin

Toffee Creamy Flavour F1744 (Butterscotch flavour)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in the original container in a cool, dry place at or below 25 °C, and keep tightly closed.

6.5 Nature and contents of container

Packed in 50 ml or 100 ml amber PVC bottles into an outer carton, and 2,5 ℓ amber HDPE bottles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pharmacorp (Pty) Ltd

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, South Africa

8. REGISTRATION NUMBER: X/11.9/394

9. DATE OF FIRST AUTHORISATION: 19 July 1993

10. DATE OF REVISION OF THE TEXT: 11 October 2022