PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

SMECTAGO® 3 g oral suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Diosmectite 3,000 g

For one sachet

Excipients with a known effect: ethanol, propylene glycol.

Contains sugar: 49,8 mg (fructose-glucose-sucrose) per sachet

Contains sweetener: sucralose 0,0375 g per sachet

This medicine contains 22,4 mg propylene glycol (E1520) and 13 mg ethanol in each sachet.

Preservative: Potassium sorbate 0,1 %

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

A beige to light beige suspension, with a characteristic odour of caramel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acute diarrhoea in children above 8 years old, in addition to oral rehydration and in adults.

Symptomatic treatment of chronic functional diarrhoea in adults.

Symptomatic treatment of pain associated with functional bowel diseases in adults.

4.2 Posology and method of administration

Posology

Treatment of acute diarrhoea:

In children from 8 years of age: 4 sachets per day for 3 days, then 2 sachets per day for 4 days.

In adults: 3 sachets per day for 7 days maximum.

Other indications:

In adults: 9 grams (3 sachets) per day.

Method of administration

Oral route

The suspension can be liquefied by kneading the sachet between the fingers before opening it.

The contents of the sachet may be swallowed undiluted or mixed into some water before drinking.

Preferably administer between meals.

In children, the contents of the sachet can be mixed with a little water in a feeding bottle or mixed with semi-liquid food, such as broth, compote, puree, baby food.

In adults: the contents of the sachet can be mixed into half a glass of water.

4.3 Contraindications

Hypersensitivity to diosmectite or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Diosmectite must be used with caution in patients with a history of severe chronic constipation.

In infants and children below 8 years, the use of **SMECTAGO** should be avoided.

The reference treatment in acute diarrhoea is oral rehydration solution (ORS).

In children above 8 years, acute diarrhoea must be treated in conjunction with early administration of an oral rehydration solution (ORS), to avoid dehydration. The chronic use of **SMECTAGO** should be avoided.

In adults, treatment does not dispense with rehydration, if this is considered to be necessary.

The amount of rehydration by oral rehydration solution or intravenously must be adapted to the intensity of the diarrhoea, and the patient's age and characteristics.

The patient must be informed of the need to:

Rehydrate with plenty of salty or sweet fluids, to make up for fluid loss due to diarrhoea (the average daily water requirement in an adult is 2 litres);

Keep up food intake while the diarrhoea persists:

- excluding some foods, especially raw vegetables and fruit, green vegetables, spicy dishes as well as frozen foods or drinks;
- preferring grilled meat and rice.

Hypersensitivity reactions, including rashes, urticaria, pruritus and angioedema have also been documented in patients treated with diosmectite through pharmacovigilance reporting.

SMECTAGO contains ethanol (alcohol), 13 mg per sachet, with a total of 52 mg per daily dose for a maximum posology of 4 sachets.

SMECTAGO contains 22,4 mg of propylene glycol in each sachet, which is equivalent to 89,6 mg per daily dose for a maximum daily posology of 4 sachets.

Contains sugar: 49,8 mg (fructose-glucose-sucrose) per sachet

Contains sucrose, glucose and fructose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take **SMECTAGO.**

Contains sucrose, glucose and fructose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

The absorbent properties of diosmectite, as contained in **SMECTAGO,** could interfere with absorption time and/or rate of co-administered substances, so it is recommended that other medicines are not administered at least two hours before **SMECTAGO** intake.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited data (less than 300 pregnancies) on the use of **SMECTAGO** in pregnant women.

Studies in animals are insufficient to conclude on reproductive toxicity.

SMECTAGO is not recommended during pregnancy.

Breastfeeding

There is limited data on the use of **SMECTAGO** during breastfeeding.

SMECTAGO is not recommended during breastfeeding.

Fertility

The effect on fertility in humans has not been studied.

4.7 Effects on ability to drive and use machines

There have been no studies on the ability to drive vehicles and operate machines with **SMECTAGO**.

However, it is expected that there is a negligible or zero effect.

4.8 Undesirable effects

a. Summary of the safety profile

The safety of **SMECTAGO** was assessed in pivotal clinical studies and post-marketing surveillance. The most frequently reported adverse drug reaction was constipation.

b. Tabulated summary of adverse reactions

Adverse reactions are presented below by system organ class and absolute frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness

MedDRA system organ class	**Frequency**	**Adverse reactions**
Immune system disorders	Unknown	Hypersensitivity
Gastrointestinal disorders	Common	Constipation
	Uncommon	Vomiting
Skin and subcutaneous tissue disorders	Uncommon	Rash
	Rare	Urticaria
	Unknown	Angioedema, pruritus

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. Health care providers are asked to report any suspected adverse reactions 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

4.9 Overdose

Overdose may lead to severe constipation or a bezoar.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class: OTHER INTESTINAL ADSORBENTS, ATC code A07BC05.

Class: 11.10 Medicines acting on gastro-intestinal tract – Others.

Diosmectite has been demonstrated in Clinical Pharmacology:

- to adsorb intestinal gas in adults

-to restore normal mucosal permeability in a clinical study performed in children with gastroenteritis.

Thanks to its leaflet structure and high plastic viscosity, diosmectite has a powerful coating property on the gastrointestinal mucosa.

The combined results of the 2 double-blind randomized studies that compare the efficacy of **SMECTAGO** against placebo and which included 602 patients aged between 1 and 36 months, suffering from acute diarrhoea, demonstrate a significant reduction in stool output emitted during the first 72 hours, in the group of patients treated by **SMECTAGO**, in addition to oral rehydration.

5.2 Pharmacokinetic properties

Given the structure of diosmectite, **SMECTAGO** is confined to the luminal side of the epithelium. It is neither absorbed nor metabolised.

Diosmectite is eliminated in the faeces through the process of normal intestinal transit.

5.3 Preclinical safety data

The pre-clinical safety data, obtained from standard acute toxicity studies and at repeated doses, and from genotoxicity studies show no evidence of particular risk to humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan gum, citric acid monohydrate, ascorbic acid, potassium sorbate, sucralose, chocolate-caramel flavour*, purified water.

* Composition of chocolate-caramel flavouring: mixture of natural and synthetic flavourings, caramel colour (E 150d), caramelized sugar syrup (49,8 mg fructose-glucose-sucrose), propylene glycol (E1520), water, ethanol, caffeine (47 ppm).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

10 g in sachet (polyethylene teraphtalate, aluminium, polyethylene teraphtalate, polyethylene).

Box of 12, 30 or 60 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

1685

8 REGISTRATION NUMBER

51/11.10/1000

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 August 2021

10 DATE OF REVISION OF THE TEXT

24 August 2021

Namibia:
Scheduling TBA
Registration no.: TBA