PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

SMECTA® ORANGE-VANILLA 3 g powder for oral suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Diosmectite 3,000 g
For one sachet of 3,760 g.
Contains sugar: glucose monohydrate 0,679 g, sucrose 27 mg
Contains sweetener: Saccharin sodium 0,021 g
Contains 13 mg ethanol per sachet
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspensions.

Greyish-white to ochre powder, with slightly reminiscent odour of orange when preparing the suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acute diarrhoea in children above 2 years, 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: 2 years and older: 4 sachets per

day for 3 days, then 2 sachets per day for 4 days.

In adults: 3 sachets per day for 7 days.

Other indications:

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

Method of administration

Oral route

The contents of the sachet must be mixed in suspension, just before use.

In children, the contents of the sachet can be mixed in a feeding bottle of 50 ml of water to be given at intervals during the day, 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 2 years, the use of **SMECTA ORANGE-VANILLA** should be avoided.

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

In children above 2 years, acute diarrhoea must be treated in conjunction with early administration of an oral rehydration solution (ORS), to avoid dehydration. The chronic use of **SMECTA ORANGE-VANILLA** 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

SMECTA ORANGE-VANILLA contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase/isomaltase insufficiency, should not take this medicine.

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

4.5 Interaction with other medicines and other forms of interaction

The absorbent properties of diosmectite, as contained in **SMECTA ORANGE-VANILLA**, could interfere with absorption time and/or rate of co-administered substances, so it is recommended that other medicines are administered at least two hours before administration of **SMECTA ORANGE-VANILLA.**

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited data (less than 300 pregnancies) on the use of **SMECTA ORANGE-VANILLA** in pregnant women.

Studies in animals are insufficient to conclude on reproductive toxicity.

SMECTA ORANGE-VANILLA is not recommended during pregnancy.

Breastfeeding

There is limited data on the use of **SMECTA ORANGE-VANILLA** during breastfeeding.

SMECTA ORANGE-VANILLA 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 this drug. 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 **SMECTA ORANGE-VANILLA** 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, pruritis

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.

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 **SMECTA ORANGE-VANILLA** 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 **SMECTA ORANGE-VANILLA**, in addition to oral rehydration.

5.2 Pharmacokinetic properties

Given the structure of diosmectite, **SMECTA ORANGE-VANILLA** 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

Glucose monohydrate, saccharin sodium, orange flavouring*, vanilla flavouring**.

*Composition of orange flavour: maltodextrin, sucrose, arabic gum (E414), mono- and diacetyltartric esters of mono- and diglycerides of fatty acids (E472e), silicium dioxide (E551), orange flavour.

*Composition of vanilla flavour: maltodextrin, sucrose, glyceryl triacetate (E1518), silicium dioxide (E551), ethyl alcohol, soya lecithin (E322), vanilla flavour.

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

Cartons containing 10 sachets (Kraft paper, Aluminum foil, Polyethylene) containing 3,76 g of powder.

6.6 Special precautions for disposal

Store at or below 25 °C.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Litha Pharma (Pty) Ltd

106 16th Road

Midrand

1685

8 REGISTRATION NUMBER

51/11.10/1002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 September 2021

10 DATE OF REVISION OF THE TEXT

21 September 2021

Namibia:
Scheduling TBA
Registration no.: TBA
Botswana:
Listing number: C1300826