PACKAGE INSERT

smectaGo®

INFORMATION ABOUT THIS MEDICINE

Name:
SMECTAGO® 3g, oral suspension in sachet.

Composition:
Active substance is:
Diosmectite .....3 g in each sachet.

Excipients:
Xanthan gum, hydrochloric acid, potassium sorbate, sodium benzoate, sucralose, caramel cocoa flavour*, purified water.
* Composition of caramel cocoa flavouring: mixture of natural and synthetic flavourings, caramel colour (E 150d), caramelized sugar syrup, propylene glycol (E 1520), water, ethanol, caffeine.

Pharmaceutical Form and Pack Size
Ready to drink oral suspension.
Box of 12 sachets.

Description
SMECTAGO® is a beige to light beige homogeneous suspension with a characteristic odour of caramel.

Pharmaco-therapeutic Classification
Antidiarrheal
Gastro-intestinal protectant
(A: Alimentary tract and metabolism)
Pharmacotherapeutic class: OTHER INTESTINAL ADSORBENTS. ATC code: A07BC05 (A: Digestive tract and metabolism).

Pharmacodynamic Properties:
Due to its leaflet structure and its high plastic viscosity, SMECTAGO® possesses a powerful coating property on the gastrointestinal mucosa. By interacting with glycoprotein of mucus, SMECTAGO® increases the resistance of the mucosal gel in response to aggressive agents.
By its action on the gastrointestinal mucous barrier and its high binding capacity, SMECTAGO® protects the gastrointestinal mucosa. SMECTAGO® is radiolucent, does not colour the stools and, at usual doses, does not modify the physiological intestinal transit time.

Pharmacokinetic Properties:
According to structure of dioctahedral smectite (active ingredient), SMECTAGO® is neither absorbed nor metabolized.

INDICATIONS
- Treatment of acute diarrhea in adults and children above 2 years, in addition to oral rehydration.
- Symptomatic treatment of chronic functional diarrhea in adults.
- Symptomatic treatment of pain associated with functional bowel disease in adults.

CONTRAINDICATIONS
Hypersensitivity to diosmectite or to one of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS
Diosmectite must be used with care in patients with a history of severe chronic constipation. In infants and children below 2 years, the use of SMECTAGO® should be avoided. The reference treatment in acute diarrhea is oral rehydration solution (ORS). In children above 2 years, acute diarrhea 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, the 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 diarrhea, and the patient's age and characteristics. The patient must be told of the need to rehydrate with plenty of salty or sweet fluids, to make up for fluid loss due to diarrhea (the average daily water requirement in an adult is 2 liters);
- Keep up food intake while the diarrhea persists: excluding some foods, especially raw vegetables and fruit, green vegetables, spicy dishes as well as frozen food or drinks; or preferring grilled meat and rice.

SMECTAGO® contains 13mg of ethanol (alcohol) in each sachet. The amount per sachet is equivalent to less than 0.325 ml of beer or 0.13 ml of wine.
This drug contains 22.4 mg of propylene glycol (E 1520) in each sachet. This drug contains 15 mg of sodium benzoate in each sachet.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

DRUG INTERACTIONS
As the adsorbent properties of this product may interfere with the rates and/or levels of absorption of other substances, it is recommended not to administer any other drugs at the same time as SMECTAGO®

PREGNANCY AND BREASTFEEDING
SMECTAGO® is not recommended during pregnancy and breastfeeding.

DOSAGE ADMINISTRATION
Recommended Dosage:
Treatment of Acute Diarrhea
In children from 2 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. In practice, the daily dose can be doubled at the start of treatment.
Other Indications:
In Adults:
An average of 3 sachets a day.

Method of Administration
SMECTAGO® is taken orally and is a ready to drink preparation. The content of the sachet can be swallowed directly. Massage the sachet before opening it. Each sachet should only be used once after opening

UNDESIRABLE EFFECTS
The most commonly reported adverse reaction during treatment is constipation, occurring in approximately 7% of adults and approximately 1% of children. If constipation occurs, diosmectite should be discontinued, and if necessary re-started at a lower dose. The table below lists adverse drug reactions reported from clinical trials and from post-marketing sources. Their frequencies are defined according to the following convention: 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), Unknown (cannot be estimated from the available data).

Adverse Drug Reactions Identified From Clinical trials and Post-Marketing Sources

System Organ Class	Frequency	Adverse reaction
Gastrointestinal disorders	Common*	Constipation
	Uncommon*	Vomiting
Skin and subcutaneous tissue disorders	Uncommon*	Rash
	Rare*	Urticaria
	Unknown	Angioedema, Pruritus
Immune system disorders	Unknown	Hypersensitivity

* Frequency estimated from incidence rates in clinical trials

EFFECTS ON ABILITY TO DRIVE VEHICLES AND OPERATE MACHINES
Not applicable.

OVERDOSE
Overdose may lead to severe constipation, vomiting or bezoar. Bezoar is a solid mass of indigestible material that accumulates in your digestive tract, sometimes even causing a blockage.
Symptoms are usually mild in intensity, and there is good recovery when Diosmectite dose is decreased or discontinued.
In case of overdose, treatment should be decreased or discontinued, particularly in case of vomiting.

Management should be symptomatic and supportive. If symptoms persist or worsen the patient should be advised to consult a doctor

STORAGE
SMECTAGO® should be kept in a dry place, below 30°C.
As with all medicines, SMECTAGO® should be kept in a safe place where children cannot reach it. Do not exceed the expiry date indicated on this pack.

PRODUCT REGISTRATION HOLDER:
Zuellig Pharma Sdn Bhd
No. 15, Persiaran Pasak Bumi, Sek. U8,
Perindustrian Bukit Jelutong
40150, Shah Alam
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MANUFACTURER:
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20 rue Ethe Virton 28100 Dreux – France

DATE OF LAST REVISION OF THIS LEAFLET
Aug 2025

Cirrus

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