INFORMATION ABOUT THIS MEDICINE

SMECTA 3 g strawberry

Powder for oral suspension in sachet

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

Excipients:
Monohydrated glucose, sodium saccharin, strawberry flavour*.
*Composition of the strawberry flavour: maltodextrin, propylene glycol, gum Arabic, mixture of natural and synthetic flavours.

Pharmaceutical Form and Pack Size
Powder for oral suspension in sachet.
Box of 12 sachets.

Description
Greyish-white to ochre powder, with slightly reminiscent odour of strawberry (before and after reconstituted)

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, SMECTA® possesses a powerful coating property on the gastrointestinal mucosa. By interacting with glycoprotein of mucus, SMECTA® 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, SMECTA® protects the gastrointestinal mucosa. SMECTA® 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), SMECTA® is neither absorbed nor metabolized.

INDICATIONS
- Treatment of acute diarrhoea in adults and children above 2 years, in addition to oral rehydration.
- Symptomatic treatment of chronic functional diarrhoea in adults.
- Symptomatic treatment of pain associated with functional bowel diseases 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 SMECTA STRAWBERRY 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 3 g STRAWBERRY 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 diarrhoea, 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 diarrhoea (the average daily water requirement in an adult is 2 liters);
- 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.

This medicinal product contains glucose. Its use is not recommended in patients presenting with glucose or galactose malabsorption syndrome.

This medicinal product contains 0.128 mg of propylene glycol in each sachet.

DRUG INTERACTIONS
The absorbent properties of this product could interfere with absorption times and/or rates of another substance, so it is recommended that other drugs are not administered at the same time as SMECTA 3 g STRAWBERRY (more than 2 hours, if possible).

PREGNANCY AND BREASTFEEDING
SMECTA 3 g STRAWBERRY is not recommended during pregnancy and breastfeeding.

DOSAGE ADMINISTRATION
Recommended Dosage:
Treatment of acute diarrhoea:
In children of 2 years of age and above:
4 sachets per day for 3 days, then 2 sachets per day for 4 days.
In adults: on average, 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 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 50 ml of water.

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.

Comon (may affect up to 1 in 10 people)
- Constipation

Uncommon (may affect up to 1 in 100 people)
- Rash
- Vomiting

Rare (may affect up to 1 in 1000 people)
- Hives (itchy rash)

Not known (frequency cannot be estimated from available data)
- Symptoms of an allergic reaction such as skin redness, itching, swelling of face or throat, breathing difficulties, faintness, collapse

If you feel any of these effects, you should see a doctor immediately.

EFFECTS ON ABILITY TO DRIVE VEHICLES AND OPERATE 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.

OVERDOSE
Overdose may lead to severe constipation or a bezoar.

STORAGE
Store below 30°C.
Keep this drug out of reach and sight of children. Do not exceed the expiry date indicated on this pack.
SMECTA should be consumed immediately after mixing.

PRODUCT REGISTRATION HOLDER:
ZUELLIG PHARMA SDN BHD
No. 15, Persiaran Pasak Bumi, Sek. U8,
Perindustrian Bukit Jelutong
40150, Shah Alam
Malaysia

MANUFACTURER:
MAYOLY INDUSTRIE
20 RUE ETHE VIRTON 28100 DREUX, France

DATE OF LAST REVISION OF THIS LEAFLET
August 2025

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Cirrus

Approval Signature

Date

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