smecta®

Orange-Vanilla

Diosmectite - 3g

Before you take the medicine, please read this leaflet carefully till the end as it contains important information. If there is anything that you do not understand or if you need further information or advice, you should consult your pharmacist or doctor who will have further details.

INFORMATION ABOUT THIS MEDICINE

Name:
SMECTA® Orange Vanilla Powder for oral suspension 3 g.

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

Excipients:
Glucose monohydrate, saccharine sodium, orange-vanilla flavor (containing sucrose).
Contains ethanol 0.00798% w/w.

Pharmaceutical Form and Pack Size
Powder for oral suspension.
Box of 10, 12 or 30 sachets.

Description
SMECTA® is packed in soft, flat sachet. The product is presented as greyish-white to ochre powder, with slightly reminiscent odour of orange when preparing the oral suspension for use.

Pharmaco-therapeutic Classification
Antidiarrhoeal
Gastro-intestinal protectant
(A: Alimentary 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 diosmectite (active ingredient), SMECTA® is neither absorbed nor metabolised.

WHAT IS THE MEDICINE USED FOR

- 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

WHAT YOU SHOULD KNOW BEFORE TAKING THE MEDICINE

Special Warnings
In infants and children below 2 years: SMECTA® should not be used.
In children above 2 years: SMECTA® should be used only in the treatment of acute diarrhoea (7 days maximum), in association with early administration of an oral rehydration solution (ORS). Any chronic use of SMECTA should be avoided.
In adults: Prolonged or repeated use of SMECTA® is not recommended without medical advice.

Consult your doctor or pharmacist:

- If you have an intolerance to particular sugar(s). This medicine contains glucose, sucrose and saccharin. Its use is not recommended in patients with fructose intolerance, glucose or galactose malabsorption syndrome or sucrase/isomaltase deficiency (rare hereditary disease).
- In case of history of severe constipation.
- In case of acute diarrhoea, if your symptoms do not improve or worsen within 3 days of treatment.
- If your digestive pain is associated with fever and vomiting.

This medicine contains small amounts of ethanol (alcohol) less than 100 mg per daily dose.

Drug Interactions
As the adsorbent properties of this product may interfere with the absorption times and/or rates of other substances, it is recommended not to administer any other drugs at the same time as SMECTA®. In case of doubts, it is advisable to seek advice from your doctor or pharmacist. In order to avoid possible interactions among several medicines, you must always tell your doctor or pharmacist what prescription and non-prescription medications you are taking.

Pregnancy and Breast Feeding
SMECTA is not recommended during pregnancy and lactation. If you are pregnant, think you might be pregnant or are planning to become pregnant or are breast feeding, you should seek the advice from your doctor or pharmacist before taking this medicine.

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HOW SHOULD THIS MEDICINE BE USED

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 a day.

Method of Administration
Oral route. The contents of the sachet must be mixed into a liquid to form a suspension, just before use.
In children of 2 years of age and above:
The contents of the sachet can be added and thoroughly stirred in the feeding bottle with 50 ml of water, to be given at intervals during the day, or thoroughly mixed with a semi-liquid food: broth, stewed fruit, mashed vegetables, or baby food.
In adults: Contents of one sachet should be thoroughly stirred in half a glass of water before taking.

WHEN SHOULD THIS MEDICINE BE TAKEN

You should take this medicine preferably in between meals in other indications.

HOW LONG SHOULD YOU TAKE THIS MEDICINE FOR?

If the symptoms do not improve within 7 days, you should consult your doctor.

WHAT SIDE EFFECTS CAN THIS MEDICINE CAUSE

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects that can occur with SMECTA® are listed below according to their frequency.
Common (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 allergic reaction such as skin redness, itching, swelling of face or throat, breathing difficulties, faintness, collapse.

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

IF YOU TAKE TOO MUCH OF THIS MEDICINE

Taking too much SMECTA may cause constipation. The constipation usually disappears when treatment is stopped or when the dose is reduced. Ask your doctor or pharmacist.

HOW TO STORE THIS MEDICINE

SMECTA® should be kept in a dry place, 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.

DATE OF LAST REVISION OF THIS LEAFLET

August 2025

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

Babies and Children:
The contents of the sachet can be added and thoroughly stirred in the feeding bottle with 50 ml of water, to be given at intervals during the day, or thoroughly mixed with a semi-liquid food: broth, stewed fruit, mashed vegetables or baby food.

Adults:
3 sachets per day for 7 days
Contents of one sachet should be thoroughly stirred in 50ml of water before taking.

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Approval Signature		Customer	Mayoly Spindler Laboratories			Colours Used	Fonts Used 8pt
Date		SAP Code	7N00560ID			Keyline (Non-Printing)	Futura
		SAP Description	NOT M SMECTA OR MY			PANTONE 2747 C	
		Proof / Iteration	2			Technical Info (Non-Printing)	
		Artwork Type	Leaflet			Cirrus_Info_Box	
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		Size	210mm x 180mm				
		Specification Ref	N/A				
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