

# Smecta® Orange-Vanilla Flavour Powder for Oral Suspension 3g

Diosmectite 3g

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## What SMECTA® is 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

## How SMECTA® works

The active substance contained in SMECTA® is dioctahedral smectite which belongs to a group of antidiarrheal gastro-intestinal protectant.

The antidiarrheal gastro-intestinal protectant activity is due to its 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. SMECTA® is neither absorbed nor metabolized.

## Before you take SMECTA®

### When you must not take it

- If you are suffering from fructose intolerance,
- If you are suffering from glucose and galactose malabsorption syndrome or sucrose/ somaltase deficiency.

- In infants and children below 2 years old, the use of SMECTA® should be avoided.
- The choric use of SMECTA® should be avoided
- SMECTA® is not recommended during pregnancy and breastfeeding.
- Hypersensitivity to diosmectite or to one of the excipients

### Before you start to take it

- If you are pregnant or breast-feeding, contact your doctor before using SMECTA®.

### Taking other medicines

It is recommended not to take any other drugs at the same time. Please tell your doctor or pharmacist if you are taking any prescription and non-prescription medications.

## How to take SMECTA®

### How much to take

Treatment of Acute Diarrhoea

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

Adults:

An average of 3 sachets per day for 7 days. In practice, the daily dose can be doubled at the start of treatment.

Other Indications:

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

For Children and infants, dissolve the content of the sachet in the feeding bottle with 50ml of water or mixed with a semi-liquid food, such as broth, compote, puree, baby food.

For adults

Dissolve the content of the sachet in 500ml of water.

### When to take it

SMECTA® should be taken during the day.

### How long to take it

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

### If you forget to take it

Do not take a double dose to make up for the forgotten dose.

### If you take too much (overdose)

Symptoms of overdose reported include constipation and bezoar.

## While you are taking SMECTA®

### Things you must do

Consult your doctor if you are pregnant or breast-feeding.

SMECTA® must be used with care in patients with a history of severe chronic constipation.

In children above 2 years, acute diarrhoea must be treated in conjunction with early administration of an oral rehydration solution (ORS), to avoid dehydration.

Rehydrate with plenty of salty or sweet fluids, to make up for fluid loss due to diarrhoea.

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; or preferring grilled meat and rice.

### Things you must not do

Not to administer any other drugs at the same time.

### Things to be careful of

If constipation occurs, diosmectite should be discontinued, and if necessary re-started at a lower dose.

## Side effects

The most commonly reported adverse reaction during treatment is constipation,

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

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

### **Storage and disposal of SMECTA®**

To be stored in a dry place, below 30° C.

Do not take SMECTA® after the expiry date which is stated on the carton or sachet.

### **Product description**

#### *What it looks like?*

SMECTA® is greyish-white to ochre powder, with slightly reminiscent odour of orange.

SMECTA® is packed in soft, flat sachet; 1 box of 10, 12 or 30 sachets.

#### *Ingredients*

Active ingredient: 3g of Diosmectite

Excipients: Glucose monohydrate, saccharine sodium, orange-vanilla flavour (containing sucrose)

#### *MAL No.*

MAL10053679X

### **Manufacturer**

Beaufour Ipsen Industrie,  
rue Ethe Virton 28100, Dreux, FRANCE.

### **Product Registration Holder**

EP PLUS GROUP SDN. BHD.  
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### **Date of revision**

December 2019

### **Serial number**

NPRA(R2/1)191216/305