

## DRUG IDENTIFICATION

**Name:**  
SMECTA®, powder for oral suspension.

## Composition

The active substance is  
Dioctahedral Smectite.....3 g, in each sachet  
The other ingredients are:  
Glucose monohydrate, saccharin sodium,  
orange-vanilla flavour (containing sucrose)  
Per sachet of 3.76g

## Pharmaceutical form

Powder for oral suspension.  
Box of 10 or 30 sachets.

## Pharmaco-therapeutic classification

Antidiarrheal  
Gastro-intestinal protectant  
(A: Alimentary tract and metabolism).

## PHARMACOLOGICAL PROPERTIES

### 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 glycoproteins 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 color the stools and, at usual doses, does not modify the physiological intestinal transit time.

### Pharmacokinetic properties

According to structure of diosmectite, SMECTA is not absorbed nor metabolized.

## INDICATION

Symptomatic treatment of pains associated with oesogastroduodenal and colonic diseases.  
Treatment of acute and chronic diarrhoea particularly in children.  
The treatment does not dispense with rehydration, should this prove to be necessary.  
The extent of rehydration and route of

administration (p.o. or i.v.) must be adapted to the severity of the diarrhoea, and the age and clinical context of the patient.

## SIDE EFFECTS

Very rare cases of development or aggravation of constipation have been reported; treatment was able to be continued after decreasing the dosage.  
REPORT ANY SIDE EFFECT NOT DESCRIBED IN THIS NOTICE TO YOUR PHYSICIAN OR YOUR PHARMACIST.

## PRECAUTIONS!

**Special warnings**  
If the symptoms do not improve within 7 days, consult your physician.  
If pain is associated with fever or vomiting, consult your physician.  
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.  
Owing to the presence of glucose and saccharose, this medicinal product is contraindicated in patients with a fructose intolerance, glucose and galactose malabsorption syndrome or sucrose/somaltase deficiency (rare hereditary diseases).

## 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 SMECTA.  
IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL DRUGS, YOU MUST SYSTEMATICALLY REPORT ANY OTHER ONGOING TREATMENT TO YOUR PHYSICIAN OR CHEMIST. IN CASE OF DOUBT, IT IS IMPERATIVE TO TAKE A MEDICAL OR A PHARMACIST ADVICE.

## Pregnancy, breast feeding

IN GENERAL, DURING PREGNANCY OR BREAST FEEDING, A MEDICAL OR A CHEMIST ADVICE SHOULD ALWAYS BE SOUGHT BEFORE TAKING ANY DRUG.

## PSOLOGY AND METHOD OF ADMINISTRATION

### Children

under the age of 1 year: 1 sachet per day  
between 1 and 2 years : 1 to 2 sachets per day  
over the age of 2 years: 2 to 3 sachets per day

Contents of sachet can be added to the baby's bottle containing 50 ml of water to be given during the day or can be mixed with a semi liquid food: pap, compote, puree, baby food.

### Adults

An average of 3 sachets per day, mixed with half a glass of water.  
In case of acute diarrhea, the daily dosage can be doubled at the beginning of treatment.

## Rhythm and time of administration

To administer preferably:  
- After meals in oesophagitis,  
- Between meals in other indications.

## STORAGE

*Do not exceed the expiry date indicated in clear on the packaging.*  
KEEP OUT OF CHILDREN'S REACH.

## LEAFLET UPDATE

FEB 2009

## Marketing Authorisation holder

BEAUFOR IPSEN PHARMA  
24 rue Erlanger  
75016 PARIS, FRANCE

## Manufacturer

BEAUFOR IPSEN INDUSTRIE  
rue Ethe Virton  
28100 DREUX, FRANCE

### babies



**Under 1 year:**  
1 sachet per day  
In a baby's bottle containing 50 ml water to be given during the day.

### children



**Between 1 and 2 years**  
1 to 2 sachets per day

**Over 2 years**  
2 to 3 sachets per day  
To mix if necessary with a semi liquid food (pap, compote, purée, baby food).

### adults



**3 sachets per day**  
To dilute with half a glass water.