

**Please read this leaflet carefully and in full, before using this medication.**

- Keep it safe, you may need to refer to it at a later date.
  - If you have any other questions or any doubts, please consult your doctor or pharmacist.
- This medication has been prescribed for you personally. Never give it to anyone else, even if they have identical symptoms, as it may prove harmful.

## 1. IDENTIFYING THE MEDICATION

### a) Composition

The active substance is diosmectite: 3g per sachet  
The other components are:  
Glucose monohydrate, saccharin sodium, orange vanilla flavour (containing sucrose).

### b) Pharmaceutical form

Powder for oral suspension in sachet  
Box containing 12 sachets

### c) Pharmaco-therapeutic class

Other intestinal adsorbents

## 2. WHEN IS THIS MEDICATION USED?

### (Therapeutic indications)

This medication is indicated in the:

- Symptomatic treatment of acute diarrhea in infants and children (in addition to oral rehydration) and in adults;
- Symptomatic treatment of chronic diarrhea;
- Symptomatic treatment of pain associated with oesogastroduodenal and colic problems.

## 3. WARNING

### a) When should this medication not be used? (Contra-indications)

This medication **MUST NOT BE USED**, in the following cases:

- Allergy to diosmectite or to one of the other components of this medication;
- If you have fructose intolerance (rare hereditary illness), due to the presence of glucose and sucrose.

### b) Special precautions and specific instructions

If the problem does not disappear within 7 days, consult your doctor.

If the pain is associated with a high temperature or vomiting, consult your doctor immediately. Diosmectite must be used with caution if you have a history of severe constipation.

In children and infants, the treatment of acute diarrhea must be accompanied by the early administration of an oral rehydration solution (ORS) to avoid dehydration.

This treatment is in addition to the following dietary rules:

- Rehydrate with plenty of salty or sweet fluids, to make up for the loss of the fluid, due to the diarrhea (the daily mean intake of water for an adult is 2 litres)
- Maintaining food intake during the bout of diarrhea, excluding certain supplements and, in particular, raw vegetables, fruit, green vegetables, spicy food and frozen foods and drink
- Eating grilled meats and rice.

### c) Interaction with medications and other interactions

To avoid any interactions between several medications, you must inform your doctor or pharmacist of any other treatment you are undergoing.

As a precaution, you should not take any other medication whilst taking this medication.

### KEEP OUT OF REACH AND SIGHT OF CHILDREN.

### d) Pregnancy / Breastfeeding

This medication will only be used during pregnancy, if your doctor prescribes it.

If, during the treatment, you find that you are pregnant, consult your doctor and he will assess whether or not you should continue the treatment.

In general, during pregnancy and breastfeeding, you should always ask the advice of your doctor or pharmacist before taking any medication.

### e) List of excipients, an awareness of which is required for certain patients to use the medication safely

Glucose, sucrose.

## 4. HOW TO USE THIS MEDICATION

### a) Dosage

#### Treatment of acute diarrhea

##### Infants and children:

- Up to one year: 2 sachets a day for 3 days, then 1 sachet a day

- After 1 year: 4 sachets a day for 3 days, then 2 sachets a day

##### Adults:

An average of 3 sachets per day. In practice, the daily dosage can be doubled at the beginning of the treatment.

### Other indications:

#### Infants and children:

- Up to one year: 1 sachet a day
- Between 1 and 2 years: 1 to 2 sachets a day
- After 2 years: 2 to 3 sachets a day

##### Adults:

An average of 3 sachets a day

### b) Method of administration

Orally

The contents of the sachet must be mixed in suspension directly before use.



##### Infants and children:

The contents of the sachet may be mixed in a bottle of 50ml of water to be given during the day, or mixed with a semi-liquid food, such as broth, compote, puree, baby food...



##### Adults:

The contents of the sachet may be mixed with half a glass of water.

Preferably to be taken:

- After meals, in case of oesophagitis
- Between meals, for other indications.

### c) What to do in the event of the overdose

If you take too much Smectalia®, powder for oral suspension, contact your doctor or pharmacist immediately.

### d) What to do if you forget to take one or more doses

If you forget to take Smectalia®, powder for oral suspension, do not take a double dose to make up for the single dose you have forgotten to take.

## 5. ADVERSE AND EMBARRASSING EVENTS

### (Adverse effects)

As with any active ingredient, this medication can cause more or less embarrassing effects in certain people:

- Constipation, usually resolving with the reduction of the dose, but in rare cases, it can lead to the treatment being stopped;
- Flatulence;
- Vomiting.

Whilst the post-marketing experience, very rare cases of allergic reactions including urticaria, rashes, pruritis and angio-oedema have been reported.

Cases of constipation worsening have also been reported.

Inform your doctor or pharmacist of any adverse or embarrassing event that is not included in this leaflet.

## 6. CONSERVATION

Do not store above 30°C.

**Do not use after the expiry date that appears on the outer packaging**

### This is a Medicament

-A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

-The doctor and the pharmacist are the experts in medicines, their benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed for you.

-Do not repeat the same prescription without consulting your doctor.

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