

SMECTAGO[®] ORAL SUSPENSION IN SACHET

Dioctahedral Smectite 3g

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What SMECTAGO[®] is used for

- Treatment of acute diarrhoea in adults and children above 2 years, in addition to oral rehydration
- Symptomatic treatment of chronic diarrhoea.
- Symptomatic treatment of pain associated with functional bowel disease in adults.

How SMECTAGO[®] works

The active substance contained in SMECTAGO[®] 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, SMECTAGO[®] increases the resistance of the mucosal gel in response to aggressive agents. SMECTAGO[®] is neither absorbed nor metabolized.

Before you take SMECTAGO[®]

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, the use of SMECTAGO[®] should be avoided.
- The chronic use of SMECTAGO[®] should be avoided.
- SMECTAGO[®] is not recommended during pregnancy and breastfeeding

Before you start to take it

- Please consult your doctor.

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 SMECTAGO[®]

How much to take

Treatment of Acute Diarrhoea

- In children from 2 years of age:
- 4 sachets per day for 3 days, then 2 sachets per day for 4 days

In Adults:

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

SMECTAGO[®] is taken orally and is a ready to drink preparation. The content of the sachet can be swallowed directly. Massage the sachet before opening it. Each sachet should only be used once after opening.

When to take it

SMECTAGO[®] should be taken during the day and preferably in between meals.

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

N/A

If you take too much (overdose)

Symptoms of overdose reported include constipation, vomiting and bezoar. Symptoms are usually mild in intensity, and there is good recovery when SMECTAGO[®] dose is decreased or discontinued.

While you are taking SMECTAGO[®]

Things you must do

SMECTAGO[®] must be used with care if you have 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 (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; 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

In case of overdose, treatment should be decreased or discontinued, particularly in case of vomiting. Management should be symptomatic and supportive. If symptoms persist or worsen please consult your doctor.

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. However, it is expected that there is a negligible or zero effect.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of SMECTAGO[®]

Keep in a dry place, below 30° C.

As with all medicines, SMECTAGO[®] should be kept in a safe

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place where children cannot reach it. Do not exceed the expiry date indicated on this pack.

Product description

What it looks like?

SMECTAGO[®] is a beige to light beige homogeneous suspension with a characteristic odour of caramel.

SMECTAGO[®] is packed in sachet; 1box of 12 sachets.

Ingredients

Active ingredient: 3g of Dioctahedral Smectite

Excipients: Caramel cocoa flavour (contains alcohol 0.13% w/w.), ascorbic acid, citric acid monohydrate, xanthan gum, potassium sorbate (as preservative 0.1% w/w), sucralose and purified water.

MAL No.

MAL10053679X

Manufacturer

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Product Registration Holder

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