PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

SMECTA® ORANGE-VANILLA Powder for Oral suspension

Diosmectite 3 g

Contains sugar:

glucose monohydrate 0,679 g per sachet

sucrose 27 mg per sachet

Contains sweetener: Saccharin sodium 0,021 g per sachet

Contains 0, 3 mg ethanol per sachet

Read all of this leaflet carefully because it contains important information for you/your child

SMECTA ORANGE-VANILLA is available without a doctor's prescription, for you/your child to treat a mild illness. Nevertheless, you/your child still need to use SMECTA ORANGE-VANILLA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SMECTA ORANGE-VANILLA with any other person.
- Ask your/your child's healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your/your child's symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What SMECTA ORANGE-VANILLA is and what it is used for
2. What you need to know before you take SMECTA ORANGE-VANILLA
3. How to take SMECTA ORANGE-VANILLA

4. Possible side effects
5. How to store SMECTA ORANGE-VANILLA
6. Contents of the pack and other information

1. What SMECTA ORANGE-VANILLA is and what it is used for

SMECTA ORANGE-VANILLA contains an active substance: diosmectite.

Diosmectite is a natural purified clay that covers the digestive mucosa.

SMECTA ORANGE-VANILLA is indicated in the treatment of:

- Acute diarrhoea in children above 2 years of age in addition to oral rehydration solution, and in adults;
- Chronic diarrhoea (long-term diarrhoea) in adults;
- Pain associated with functional bowel diseases in adults.

2. What you need to know before you/your child take/s SMECTA ORANGE-VANILLA

Do not take/administer SMECTA ORANGE-VANILLA:

- if you/your child are/is hypersensitive (allergic) to diosmectite or any of the ingredients of SMECTA ORANGE-VANILLA (see section 6).

Warnings and precautions

In children above 2 years of age:

SMECTA ORANGE-VANILLA 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 ORANGE-VANILLA should be avoided.

In adults:

Prolonged or repeated use of SMECTA ORANGE-VANILLA is not recommended without medical advice.

Ask your/your child's doctor or pharmacist before taking SMECTA ORANGE-VANILLA:

- If your doctor has told you that you have an intolerance to particular sugar(s). This medicine contains two sugars (glucose and sucrose). Its use is not recommended in patients with fructose intolerance, glucose or galactose malabsorption syndrome or sucrase / isomaltase deficiency (rare hereditary diseases).
- in case of history of severe constipation.

Consult your/your child's doctor:

- In case of acute diarrhoea, if your/your child's symptoms do not improve or worsen within 3 days of treatment,
- If your diarrhoea and abdominal (tummy) discomfort are associated with fever or vomiting.

Children

SMECTA ORANGE-VANILLA should be used only in children above 2 years of age in the treatment of acute diarrhoea. It should be administered with early administration of an oral rehydration solution (ORS), to avoid dehydration. The treatment duration should not exceed 7 days.

Additional dietary rules

This treatment is supplementary to dietary rules:

- Ensure rehydration with plenty of salty or sweet drinks, to compensate for fluid loss due to diarrhoea (the average daily water requirement in an adult is 2 litres);
- Maintain food intake while the diarrhoea persists, but excluding some foods, especially raw vegetables and fruit, green vegetables, spicy dishes as well as frozen foods or drinks;
- Grilled meat and rice are preferred.

Other medicines and SMECTA ORANGE-VANILLA

Always tell your/your child's health care provider if you/your child are/is taking any other medicine. (This includes all complementary or traditional medicines).

The intake of this medicine can decrease the absorption of other medicines taken at the same time. Therefore, no other medicine should be taken at the same time as SMECTA ORANGE-VANILLA. You should follow a 2-hour interval between intake of SMECTA ORANGE-VANILLA and other medicines. Tell your/your child's doctor or pharmacist if you/your child are/is taking, have/has recently taken or could take any other medicine.

SMECTA ORANGE-VANILLA with food and drink

There is no interaction with food and drink.

Pregnancy and breastfeeding

Safety of SMECTA ORANGE-VANILLA use in pregnancy and breastfeeding has not been established. Use of SMECTA ORANGE-VANILLA in pregnancy and during breastfeeding your baby, is not recommended.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this SMECTA ORANGE-VANILLA.

Driving and using machines

However, it is unlikely that SMECTA ORANGE-VANILLA will have an effect on your ability to drive or use machines.

SMECTA ORANGE-VANILLA contains glucose and sucrose. If you/your child have/has been told by your/his/her doctor, that you/he/she have/has intolerance to some sugars, you/your child should not use SMECTA ORANGE-VANILLA. SMECTA ORANGE-VANILLA contains 0,679 g of glucose and 27 mg of sucrose per sachet. **(Editorial change)**

This medicine contains 0, 3 mg of ethanol (alcohol) per sachet, with a total of 1, 8 mg per daily dose for a maximum posology of 6 sachets. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

3. How to use SMECTA ORANGE-VANILLA

Do not share medicines prescribed for you/your child with any other person.
Always use this medicine exactly as your/your child's doctor has told you. Check with your/your child's doctor or pharmacist if you are not sure.

The usual dose is:

For the treatment of acute diarrhoea:

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

In adults: 2 sachets three times per day (6 sachets) for 4 days, then 3 sachets a day for 3 days.

For other indications:

In adults: 3 sachets per day.

Method and route of administration

Oral route.

The contents of the sachet must be mixed into a liquid to form a suspension, just before use.

In children: The contents of the sachet can be mixed in a feeding bottle with 50 mL of water to be given at intervals during the day, or mixed with a semi-liquid food, such as broth, compote, puree, or baby food.

In adults: the contents of the sachet can be mixed into half a glass of water.

If you/your child use/s more SMECTA ORANGE-VANILLA than you/he/she should

In the event of overdosage, consult your/your child's doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Taking too much SMECTA ORANGE-VANILLA may cause constipation. The constipation usually disappears when treatment is stopped or when the dose is reduced. Ask your/your child's doctor or pharmacist.

If you/your child forget/s to take SMECTA ORANGE-VANILLA

Do not take/administer a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this medicine, ask your/your child's doctor or pharmacist.

4. Possible side effects

SMECTA ORANGE-VANILLA can have side effects.

Not all side effects reported for SMECTA ORANGE-VANILLA are included in this leaflet. Should your/your child's general health worsen or if you/your child experience/s any untoward effects while taking SMECTA ORANGE-VANILLA, please consult your/your child's health care provider for advice.

Frequent

Constipation

Less frequent

Rash

Vomiting

Hives (itchy rash)

Frequency unknown

Symptoms of an allergic reaction such as skin redness, itching, swelling of face, tongue or throat, breathing difficulties, faintness, collapse.

If you/your child feel/s any of these effects, you should see a doctor immediately.

If you notice any side effects not mentioned in this leaflet, please inform your/your child's doctor or pharmacist.

Reporting of side effects

If you/your child get/s side effects, talk to your/your child's doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Acino Pharma via email on drugsafety_ZA@acino.swiss. By reporting side effects, you can help provide more information on the safety of SMECTA ORANGE-VANILLA.

5. How to store SMECTA ORANGE-VANILLA

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.
- Do not store in a bathroom.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SMECTA ORANGE-VANILLA contains

The active substance is Diosmectite 3, 000 g

The other components are: Glucose monohydrate, sodium saccharine, orange flavour*, vanilla flavour**.

*Composition of orange flavour: maltodextrin, sucrose, Arabic gum (E414), mono- and diacetyltartric esters of mono- and diglycerides of fatty acids (E472e), silicium dioxide (E551), orange flavour.

**Composition of vanilla flavour: maltodextrin, sucrose, glyceryl triacetate (E1518), silicium dioxide (E551), ethyl alcohol, soya lecithin (E322), vanilla flavour.

What SMECTA ORANGE-VANILLA looks like and contents of the pack

Greyish-white to ochre powder, with slightly reminiscent odour of orange when preparing the suspension.

This medicine is presented as a powder for oral suspension in a sachet.

Carton containing 10 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The professional information for Smecta Orange Vanilla can be accessed by scanning the QR-code below: