PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

SMECTA® STRAWBERRY Powder for Oral suspension

Diosmectite 3 g

Contains sugar – glucose monohydrate 0,721 g;

Contains sweetener: saccharin sodium 0,007 g

This medicine contains propylene glycol E1520 in a total of 0,032 g of flavourant

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

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

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

What is in this leaflet

1. What SMECTA STRAWBERRY is and what it is used for
2. What you need to know before you take SMECTA STRAWBERRY
3. How to take SMECTA STRAWBERRY
4. Possible side effects
5. How to store SMECTA STRAWBERRY
6. Contents of the pack and other information

1. What SMECTA STRAWBERRY is and what it is used for

SMECTA STRAWBERRY contains an active substance: diosmectite.

Diosmectite is a natural purified clay that covers/coats the digestive mucosa

SMECTA STRAWBERRY 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 take SMECTA STRAWBERRY

Do not take SMECTA STRAWBERRY:

- if you are hypersensitive (allergic) to diosmectite or any of the other ingredients of SMECTA STRAWBERRY (see section 6).
- If you or your infant/child have severe constipation
- If you or your child/infant have severe dehydration (severe loss of body fluids) requiring fluids and electrolytes via an intravenous infusion (drip into a vein)

Warnings and precautions

In children above 2 years:

SMECTA STRAWBERRY 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 STRAWBERRY should be avoided.

In adults:

Prolonged or repeated use of SMECTA STRAWBERRY is not recommended without medical advice.

Ask your doctor or pharmacist before taking SMECTA STRAWBERRY:

- If your doctor has told you that you have an intolerance to particular sugar(s). This medicine contains glucose. Its use is not recommended in patients with glucose or galactose

malabsorption syndrome. It may interfere with blood glucose control if you have diabetes mellitus.

- in case of history of severe constipation.

Consult your doctor:

- In case of acute diarrhoea, if your 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 STRAWBERRY 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

Treatment with SMECTA STRAWBERRY is supplementary to dietary rules:

- Ensure rehydration with plenty of salty and/or sweet drinks, or an oral rehydration solution, 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;
- Prefer grilled meat and rice.

Other medicines and SMECTA STRAWBERRY

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

The intake of SMECTA STRAWBERRY 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 STRAWBERRY. You should follow a 2-hour interval between intake of SMECTA STRAWBERRY and other medicine, if possible. Tell your doctor or pharmacist if you are taking, have recently taken or could take any other medicine.

SMECTA STRAWBERRY with food and drink

There is no interaction with food and drink.

Pregnancy and breastfeeding

Safety of SMECTA STRAWBERRY use in pregnancy and breastfeeding has not been established. Use of SMECTA STRAWBERRY in pregnancy and breastfeeding, is not recommended.

If you are pregnant or breastfeeding your baby, 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 SMECTA STRAWBERRY.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

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

SMECTA STRAWBERRY contains

Glucose. If you have been told by your doctor, that you have intolerance to some sugars, or if you have diabetes mellitus, contact your doctor before taking SMECTA STRAWBERRY.

SMECTA STRAWBERRY contains 0,721 g of glucose per sachet.

SMECTA STRAWBERRY contains 0,128 mg of propylene glycol (E1520) in each sachet, which is equivalent to 0,512 mg per daily dose for a maximum daily posology of 4 sachets.

3. How to use SMECTA STRAWBERRY

Do not share medicines prescribed for you with any other person.

Always use SMECTA STRAWBERRY exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is :

For the treatment of acute diarrhoea:

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

In adults: Three (3) sachets per day for 7 days.

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

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

If you use more SMECTA STRAWBERRY than you should

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

Taking too much SMECTA STRAWBERRY may cause constipation. The constipation usually disappears when treatment is stopped or when the dose is reduced. Ask your doctor or pharmacist.

If you forget to take SMECTA STRAWBERRY

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

If you have any further questions on the use of SMECTA STRAWBERRY, ask your doctor or pharmacist.

4. Possible side effects

SMECTA STRAWBERRY can have side effects.

Not all side effects reported for SMECTA STRAWBERRY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SMECTA STRAWBERRY, please consult your 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 feel any of these effects, you should see a doctor immediately.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SMECTA STRAWBERRY.

5. How to store SMECTA STRAWBERRY

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use SMECTA STRAWBERRY 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 STRAWBERRY contains

The active substance is Diosmectite 3, 000 g

The other components are: Glucose monohydrate, sodium saccharin, strawberry*. *Composition of strawberry flavour: maltodextrin, propylene glycol E1520, gum Arabic, mixture of natural and synthetic flavours.

What SMECTA STRAWBERRY looks like and contents of the pack

SMECTA STRAWBERRY is presented as a powder for oral suspension in sachet.

Carton containing 10 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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Midrand

1685

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Registration number

51/11.10/1001

Access to the corresponding Professional Information

To be confirmed

Namibia:
Scheduling TBA
Registration no.: TBA
Botswana:
Listing number: C1300826