



orange-vanilla flavor
Dioctahedral Smectite - 3 g

Before you start to take your medicine, please read this leaflet carefully all the way through as it contains important information.

If there is anything that you do not understand or if you need further information or advice, you should consult your pharmacist or doctor who will have further details.

INFORMATION ABOUT THIS MEDICINE

Name:

SMECTA®, powder for oral suspension.

Composition:

The active substance is

Dioctahedral Smectite.....3.00 g in each sachet

The other ingredients are:

Glucose monohydrate, saccharine sodium, orange-vanilla flavour (containing sucrose)

Pharmaceutical Form and Pack Size:

Powder for oral suspension.

Box of 10 or 30 sachets.

Description:

SMECTA® is packed in soft, flat sachet. The product is presented as off-white to light beige powder, with slightly reminiscent odour of orange when preparing the oral suspension for use.

Pharmaco-therapeutic Classification:

Antidiarrheal

Gastro-intestinal protectant

(A: Alimentary tract and metabolism)

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 glycoprotein 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 colour the stools and, at usual doses, does not modify the physiological intestinal transit time.

Pharmacokinetic Properties:

According to structure of dioctahedral smectite (active ingredient), SMECTA® is neither absorbed nor metabolized.

WHAT IS THIS MEDICINE USED FOR?

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

Fluid and electrolyte depletion may occur in patients who have diarrhoea.

The use of SMECTA® does not preclude the administration of appropriate fluid and electrolyte therapy, should this prove to be necessary.

The extent of rehydration and route of administration (orally or intravenously) must be adapted to the severity of the diarrhoea, the age and clinical context of the patient.

WHAT YOU SHOULD KNOW BEFORE TAKING THIS MEDICINE

Special Warnings:

Owing to the presence of glucose and saccharine, this medicinal product is contraindicated in patients with a fructose intolerance, glucose and galactose malabsorption syndrome or sucrase/somaltase deficiency (rare hereditary diseases).

In infants and children under 2 years of age, the use of SMECTA® should be avoided. The standard treatment for acute diarrhoea is the administration of oral rehydration solution (ORS).

In children of 2 years and above, acute diarrhoea should be treated in combination with the early administration of an oral rehydration solution (ORS) to avoid dehydration. Chronic use of SMECTA® should be avoided.

In adults, the treatment is given together with rehydration, if proven necessary.

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 case of doubts, it is advisable to seek advice from your doctor or pharmacist. In order to avoid possible interactions among several medicines, you must always tell your doctor or pharmacist what prescription and non-prescription medications you are taking.

Pregnancy and Breast Feeding:

Use of SMECTA® is not recommended due to insufficient data.

HOW SHOULD THIS MEDICINE BE USED?

Recommended Dosage

Children:

- 2 years: 1 to 2 sachets per day
- Over the age of 2 years: 2 to 3 sachets per day

Adults:

An average of 3 sachets per day for 7 days. The contents should be thoroughly stirred in 50 ml of water. In case of acute diarrhoea, the daily dosage can be doubled at the beginning of the treatment.

Method of Administration

Children:

The contents of the sachet can be added and thoroughly stirred in the feeding bottle with 50 ml of water, to be given during the day, or thoroughly mixed with a semi-liquid food: broth, stewed fruit, mashed vegetables or baby food.

Adults:

Contents of one sachet should be thoroughly stirred in 50 ml of water before taking.

WHEN SHOULD THIS MEDICINE BE TAKEN?

You should take this medicine preferably in between meals.

HOW LONG SHOULD YOU TAKE THIS MEDICINE FOR?

If the symptoms do not improve within 7 days, consult your doctor.

WHAT SIDE EFFECTS CAN THIS MEDICINE CAUSE?

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 which is not described in this leaflet to your doctor or pharmacist.

IF YOU TAKE TOO MUCH OF THIS MEDICINE

To date, very limited incidence of overdose has been reported. Symptoms of overdose reported include constipation, vomiting and bezoar.

HOW TO STORE THIS MEDICINE

SMECTA® should be kept in a dry place, at or below 25°C.

As with all medicines, SMECTA® should be kept in a safe place where children cannot reach it.

Do not exceed the expiry date indicated on this pack.

DATE OF LAST REVISION OF THIS LEAFLET

MAY 2019

Under license of IPSEN

MANUFACTURER:

BEAUFOR IPSEN INDUSTRIE

rue Ethe Virton - 28100 DREUX, FRANCE

children



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 for 7
days

*To dilute with 50 ml of
water.*

In case of acute
diarrhoea, the daily
dosage can be doubled
at the beginning of the
treatment.



思密达®

香橙云呢拿味

双八面体蒙脱石-3g

您在服用本品之前，请从始至终地仔细阅读此说明，其中含有重要的信息。
如果您有何不了解的事情或需要进一步信息或建议，请咨询您的医生或药师。

产品信息

名称：

思密达®，粉剂

成分：

活性成分：

双八面体蒙脱石 每包3g

其他成分：

葡萄糖、糖精、桔-香草香料（含蔗糖）

剂型及包装规格：

粉剂，每盒10包或30包。

性状：

思密达®装在小包内，本品为灰白色到浅米色粉末，略微有香橙味。

治疗分类：

抗腹泻药

胃肠道保护药

药理特性：

由于思密达®的片状结构和高粘塑性，它具有很强的胃肠道粘膜的覆盖能力，通过与粘液中糖蛋白相互作用，思密达®增强粘膜攻击因子的抵抗力；通过胃肠道粘膜屏障的作用及其高度粘附力，思密达®保护胃肠道粘膜。思密达®不影响X光检查。思密达®不改变大便颜色，常剂量下，不改变肠道的正常蠕动。

药代药力学：

由于双八面体蒙脱石的结构，思密达®既不被吸收也不被代谢。

思密达®用于治什么？

- 与口服补液盐合治疗2岁及以上儿童的急性腹泻。
- 治疗成人急性腹泻。
- 成人慢性功能性腹泻的症状治疗。

腹泻患者易流失液体和电解质。

思密达®不能替代补液盐法，脱水病例适当补液，其用法用量必须根据患者的腹泻程度、年龄及临床情况而定。

服用思密达®之前了解什么？

特殊警告：

本品含有葡萄糖和糖精，患有果糖不耐受、葡萄糖或半乳糖吸收障碍综合征或蔗糖-异麦芽糖酶缺陷（罕见遗传性疾病）的患者禁用。

2岁以下的儿童，应避免使用思密达®。急性腹泻的首选治方法是口服补液盐 (ORS)。

2岁及以上的儿童，急性腹泻可与早期口服补液盐（ORS）联合治，以避免脱水。避免同时用思密达®。

在成人中，如果证明有必要，可与口服补液一起治疗。

药物相互作用：

本品的吸附作用可能干扰其他药物的吸收，如需服用其他药物，建议与思密达®间隔一段时间。避免药物相互作用，您必须将正在服用的其他药物，无论是处方或非处方，告知您的医生或药师。如有疑问，请遵照医生或药师的意见。

妊娠及哺乳期：

由于资料不足，建议不要使用思密达®。

如何服用思密达®？

建议剂量

儿童：

- 2岁：每日1-2包
- 2岁以上：每日2-3包

成人：

每天平均3包，连续服7天。小袋含量可在50毫升水中彻底搅拌。

在急性腹泻治中，开始的日用量可加倍。

用法

儿童：

每包可加入到婴儿奶瓶中与50毫升水混匀或与半流食：肉/果汁，菜泥/婴儿食品混匀后服用。

成人：

每包与50毫升水混匀后服用。

何时服用思密达？

宜于两餐之间服用。

思密达服用多久？

如果症状在7日内无改善，应向您的医生咨询。

思密达可能有何副作用？

有报告极少病例出现便秘或便秘加重；减少剂量后，治疗可继续进行。

如发现有说明书中未列出的副作用，请告知您的医生或药师。

如果过量服用思密达

至今，极少有过量事件的报告。已报告的过量症状包括便秘、呕吐和胃石。

如何储存思密达

存放于干爽地方，25°C或以下。

如同所有药物，思密达®应存放于安全地方，儿童不可接触之处。

不要超过盒上指明的日期。

说明修订日期

2019年5月

根据IPSEN许可证

制造厂：

BEAUFOR IPSEN INDUSTRIE
rue Ethe Virton
28100 DREUX, FRANCE

儿童



2岁

每日1-2包

2岁以上

每日2-3包

可与半流食：肉

汁/果汁，菜泥/辅食

食品混匀后服用

成人



每日3包，连续服7天

与50毫升水混匀

后服用

在急性腹泻治疗中，开

始的日用量可加倍。