



15-03-2022
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170mm

DOCTILE[®] 3g Sachet (Dioctahedral Smectite)

QUALITATIVE AND QUANTITATIVE COMPOSITION

DOCTILE[®] 3g Sachet
Each sachet contains:
Dioctahedral Smectite MS.....3g

PHARMACEUTICAL FORM

Powder for oral suspension, Sachet.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

- Symptomatic treatment of irritable bowel syndrome in adults and gastroesophageal reflux in infants due to mucoprotective effects.
- Treatment of acute and chronic diarrhoea.

POSODOLOGY AND METHOD OF ADMINISTRATION:

Children:

- Under the age of 1 year: 1 sachet per day.
 - From 1 to 2 years: 1 to 2 sachets per day.
 - Over the age of 2 years: 2 to 3 sachets per day.
- To be administered in 2-3 divided doses.

OR

As prescribed by the physician

The contents of the sachet can be mixed in a bottle with 50ml of water or with a semi-liquid food: broth, fruit, mashed vegetables, baby food.

Adults:

An average of 3 sachets in 2-3 divided doses per day mixed in half a glass of water.
In acute diarrhoea, the daily dosage can be doubled at the beginning of treatment.

OR

As prescribed by the physician

Administer preferably after meals in oesophagitis and in between meals in other indications.

CONTRAINDICATIONS:

- Hypersensitivity to the active substance.
- Due to the presence of glucose and saccharose, this medication is contraindicated for patients who are fructose intolerant.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Treatment with dioctahedral smectite does not eliminate the need of rehydration when it is required.

The volume of rehydration and its route of administration (Oral or IV) should be adapted to the patient's age and condition as well as to the severity of diarrhoea.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

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 drug at the same time as dioctahedral smectite.

FERTILITY, PREGNANCY AND LACTATION:

Clinically, no malformation or foetotoxic effect has currently come to light. However, there is not enough evidence of pregnancies exposed to dioctahedral smectite to exclude any risk.

Consequently, given that dioctahedral smectite is not absorbed, its use could be envisaged during pregnancy only if necessary.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not known.

UNDESIRABLE EFFECTS:

Very rare cases of development or aggravation of constipation are known to be reported; treatment may be continued after decreasing the dosage.

OVERDOSE:

None

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other intestinal absorbents. **ATC Code:** A07BC05.

PHARMACODYNAMIC PROPERTIES:

Dioctahedral smectite is a double aluminum and magnesium silicate; due to its structure in leaves and its high plastic viscosity, has a significant digestive mucous covering capacity.

Dioctahedral smectite, by interacting with mucus glycoproteins, increases the mucous gel's resistance to attacks.

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Diocahedral smectite, by acting on the digestive mucous barrier and its high fixation capacity, protects the digestive mucous.
Diocahedral smectite is radio-transparent, does not colour stools and, at the usual doses, does not affect the physiological intestinal transit time.

PHARMACOKINETIC PROPERTIES:

Given the structure of diocahedral smectite, it is neither absorbed nor metabolized.

SHELF LIFE

See expiry on the pack.

AVAILABILITY

DOCTILE® 3g sachet in a pack of 30's

INSTRUCTIONS

Dosage: As advised by the physician.
To be sold on the prescription of a registered medical practitioner only.
Keep out of the reach of children.
Avoid exposure to heat, light and humidity.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.

ڈوکتائل® ۳ گرام ساشے

(ڈائوہیکٹائل سیمیکلائٹ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔ اسے ۱۵ سے ۳۰ ڈگری
سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائے گی۔



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SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
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