



# **DOCTILE<sup>®</sup>**

**(Dioctahedral Smectite)**

## **1. NAME OF THE PRODUCT**

**DOCTILE<sup>®</sup>** (Dioctahedral Smectite) 3g Sachet

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**DOCTILE<sup>®</sup>** 3g Sachet

Each sachet contains:

Dioctahedral Smectite MS.....3g

## **3. PHARMACEUTICAL FORM**

Powder for oral suspension

**Appearance:** Off white to light brown powder, smooth to touch.

## **4. CLINICAL PARTICULARS**

### **4.1. THERAPEUTIC INDICATIONS:**

- Symptomatic treatment of acute diarrhoea in children from 2 years of age in combination with oral rehydration solution and in adults.
- Symptomatic treatment of chronic functional diarrhoea in adults.
- Symptomatic treatment of pain associated with functional bowel disorders in adults.

### **4.2. POSOLOGY AND METHOD OF ADMINISTRATION:**

**Posology:**

**Treatment of acute diarrhoea:**

***For children from 2 years of age:***

- 6g (2 sachets) per day.

The dose may be doubled at the beginning of an acute episode of diarrhoea.

***For adults:***

- 9g (3 sachets) per day.

The dose may be doubled at the beginning of an acute episode of diarrhoea.

An episode of acute diarrhoea usually lasts less than 7 days.

**Treatment of other indications:**

***For adults:***

- an average of 9g (3 sachets) per day

**Method of administration:**

For oral use.



The contents of the sachet should be mixed shortly before use.

For young children: the contents of the sachet should be mixed with 50ml of water given during the day, or mixed with semi-liquid food, such as broth, compote, puree, baby food.

For older children (up to 18 years of age) and adults: the contents of the sachet should be mixed with half a glass of water.

#### **4.3. CONTRAINDICATIONS:**

Hypersensitivity to the active substance dioctahedral smectite and/or to any of the excipients.

#### **4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:**

Treatment of diarrhoea with Dioctahedral Smectite is only symptomatic. Unless the etiology of the underlying disease is known, specific therapy should be applied if necessary.

Parents/caregivers should consult a doctor before using Dioctahedral Smectite in children if:

- the child has a serious underlying illness (e.g. diabetes, kidney failure);
- the child has persistent vomiting;
- the child has frequent diarrhoea (>8 episodes per day) with increased stool volume;
- the child has signs of severe dehydration.

Patients should be advised to consult a doctor if, while taking Dioctahedral Smectite:

- in case of acute diarrhoea, there is no improvement within 48 hours and in case of chronic diarrhoea, there is no improvement within 14 days;
- symptoms do not improve or the general condition becomes worse;
- the following symptoms appear: severe vomiting or dehydration, persistent fever, abdominal bloating, blood in the stool.

The main prerequisite for the treatment of acute diarrhoea is to prevent or reduce fluid and electrolyte loss. This is especially true for children, debilitated patients, and the elderly. In these cases, the main measure is appropriate fluid and electrolyte replacement therapy. The need for rehydration with oral rehydration salt solutions, enteral (nasogastric) or intravenous rehydration, adjusted to the severity of the diarrhoea, the patient's age and health status, should always be considered.

Patients with a history of severe chronic constipation should be cautious when using Dioctahedral Smectite.

This medicinal product contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicinal product.



#### 4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

The adsorbing properties of this medicine may slow down the rate and/or reduce the extent of absorption of other substances, therefore it is not recommended to take other medicines simultaneously with Dioctahedral Smectite. A 2-hour interval between taking Dioctahedral Smectite and other medicines is recommended.

#### 4.6. FERTILITY, PREGNANCY AND LACTATION:

**Fertility:** The effect on fertility has not been evaluated.

**Pregnancy:** Dioctahedral Smectite is not recommended for use during pregnancy.

**Breast-feeding:** Dioctahedral Smectite is not recommended for use during breast-feeding.

#### 4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Dioctahedral Smectite does not affect the ability to drive or use machines.

#### 4.8. UNDESIRABLE EFFECTS:

The adverse reactions ranked under headings of system organ class and frequency using the following convention: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ); not known (cannot be estimated from the available data).

The most common side effect during treatment is constipation, which occurs in approximately 7% of adults and approximately 1% of children.

| System organ class                     | Frequency   | Side effect          |
|--|-------------|----------------------|
| Gastrointestinal disorders             | Often       | Constipation         |
| Skin and subcutaneous tissue disorders | Less common | Rash                 |
|  | Rare        | Hives                |
|  | Unknown     | Angioedema, pruritus |
| Immune system disorders                | Unknown     | Hypersensitivity     |

#### 4.9. OVERDOSE:

Overdose may cause severe constipation or bezoars.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1. PHARMACODYNAMIC PROPERTIES:

**Pharmacotherapeutic group:** Antidiarrhoeals and drugs for the treatment of intestinal infections and inflammations; intestinal content adsorbents.

**ATC code:** A07BC05

**Mechanism of action:**

Dioctahedral Smectite is an insoluble mineral clay with a high molecular weight. Due to its lamellar structure and pronounced plastic viscosity, diosmectite has strong coating properties for the gastrointestinal mucosa.

Dioctahedral Smectite binds to glycoproteins in the gastrointestinal tract mucus and increases the rheological properties of the mucus barrier. Dioctahedral Smectite forms an additional layer of mucus and thus protects against aggressive irritants and microorganisms.

**5.2. PHARMACOKINETICS PROPERTIES:**

**Absorption:** Since the active ingredient in **DOCTILE®**, Dioctahedral Smectite, is an insoluble mineral clay with a high molecular weight, it is not absorbed through the gastrointestinal mucosa and is not metabolized when taken orally.

**Elimination:** Dioctahedral Smectite is excreted in the faeces through normal intestinal transit.

**5.3. PRECLINICAL SAFETY DATA:**

Non-clinical data reveal no special hazard for humans based on conventional studies of acute and repeated dose toxicity and genotoxicity.

**6. PHARMACEUTICAL PARTICULARS****6.1. LIST OF EXCIPIENTS:**

- Dextrose Anhydrous
- Vanillin Powder
- Poly Vinyl Pyrrolidone
- Neotame Powder
- Blood Orange Flavor

**6.2. INCOMPATIBILITIES:**

Not applicable

**6.3. SHELF LIFE:**

See expiry on the pack.

**6.4. SPECIAL PRECAUTIONS FOR STORAGE:**

Do not store over 30°C and protect from heat, light and moisture.

Improper storage may deteriorate the medicine.

Keep out of reach of children.

**6.5. NATURE AND CONTENTS OF CONTAINER:**

Aluminium paper foil sachet, pack size is 30's.



- 6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:**  
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
- 6.7. DRUG PRODUCT SPECIFICATIONS:**  
SAMI's Specs.
- 7. REGISTRATION / MARKETING AUTHORISATION HOLDER**
- Manufactured by:  
 **SAMI Pharmaceuticals (Pvt.) Ltd.**  
F-95, S.I.T.E., Karachi-Pakistan  
www.samipharma.com  
Mfg Lic. No. 000072
- 8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)**  
080299
- 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**  
16<sup>th</sup> March, 2016
- 10. DATE OF REVISION OF THE TEXT**

**ڈوکٹائل®** ساشے  
(ڈائیکٹائیل سميکلائٹ)

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 ۱۵ سے ۳۰ ڈگری  
سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

R.N-05/QC/06/2026\_SmPC