

## WHAT IS CLAY?<sup>1</sup>



### ► Physical/granulometric criterion:

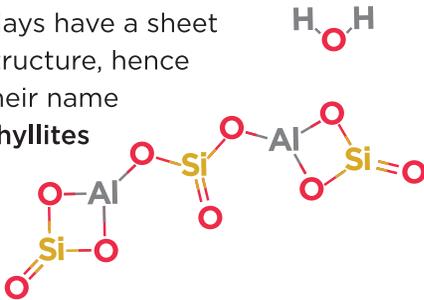
- Clays are composed of very fine particles of less than 2 micrometres

### ► Chemical criterion

- They are hydrated silicates

### ► Crystallographic & mineralogical criterion

- Clays have a sheet structure, hence their name phyllites



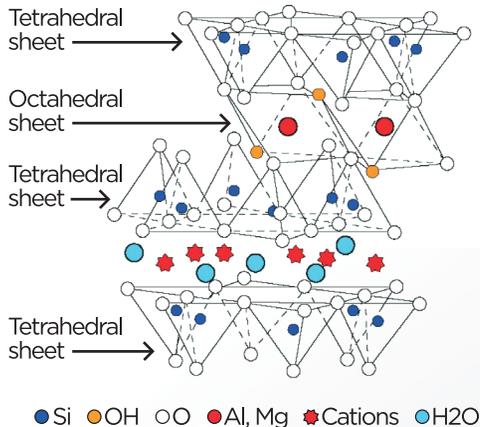
## EXAMPLE OF DIOSMECTITES

### ► Dioctahedral clay

- Montmorillonites, beidellites, nontronites

### ► Weakly bound and easily interchangeable compensating ions<sup>1-3</sup>

- Adsorption and absorption properties



### ► Fine particles and a sheet structure allowing a large surface area for interaction with the environment<sup>1</sup>

CLAY IS A **MINERAL** MADE OF ALUMINIUM SILICATES **ORGANISED IN SHEETS** COMPOSED OF VERY FINE PARTICLES

**THE PROPERTIES OF SMECTITES** EXPLAIN THEIR WIDE RANGE OF USE





Clay, a well-known natural substance with unique properties



## THE PHYSICAL AND CHEMICAL PROPERTIES OF CLAYS: ADSORPTION AND BUFFER POWER

### ► Ability of clays to fix/bind molecules, linked to:<sup>1-3</sup>

- Large surface area for interaction with the environment<sup>1</sup>
- Presence of interchangeable ions
- Stability at physiological pH and ability to capture protons

### ► Mode of action used

#### ♥ IN HEALTH



#### ▪ Gastrointestinal disorders

- Binding of pathogens, toxins, gases<sup>4</sup>

## THE PHYSICAL AND CHEMICAL PROPERTIES OF CLAYS: COATING POWER

### ► Mode of action used

#### ♥ IN HEALTH <sup>3, 6</sup>



#### ▪ Protection of the gastric or intestinal mucosa

- Keep contaminants away from skin wound

## ★ ★ ★ KEY POINTS ★ ★ ★

Clays are natural minerals that are widely present at the surface of the earth<sup>1,3</sup>

The physico-chemical properties of clays are based on their structure and underpin their modes of action

- Plasticity
- Adsorption and buffering power
- Absorption and swelling
- Coating power

The uses of clays have been known since ancient times and implicated in a number of fields

- Housing
- Industry
- Animal health
- Human health

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Clays, trusted since ancient times

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Diosmectite

## THERAPEUTIC CLAYS MUST BE EXTRACTED IN CAREFULLY SELECTED QUARRIES



### ► Criteria for the selection of deposits

- **An adequate raw material:** clay of high mineralogical purity, containing the right cations in the interlayer space, and with low electrostatic forces that will give the clay a good absorption capacity and a stable hydration capacity
- **High grade quality of the natural clay** with low level of natural impurities and allowing to obtain a high quality pure active ingredient
- **Quality homogeneity of the natural clay:** sufficient stability and high purity is necessary for industrial operation in good quality practices

ONLY QUARRIES MEETING THESE ESSENTIAL CRITERIA CAN BE USED TO PRODUCE THERAPEUTIC CLAYS FOR MEDICAL USE

## PRODUCTION OF THERAPEUTIC CLAYS MUST FOLLOW A STRICT AND CONTROLLED PROCESS



### ► Controlled purification

- Purification of the smectite clay by a long and unique wet process
- Bacteriological treatment by hot drying
- Conservation of clay properties



### ► Controlled production

- Guaranteeing integrity of the clay's properties
- Ensuring safe use of clays

THE MANUFACTURING PROCESS OF THERAPEUTIC CLAYS FOR ORAL USE IS STRICT AND CAREFULLY CONTROLLED THROUGHOUT THE PROCESS

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Diosmectite

Symptomatic treatment of; Acute diarrhoea in children and infants in addition to Oral rehydration and in adults; Chronic diarrhoea; Pain associated to oesophagus and gastroduodenal and colic disease<sup>5</sup>; Full prescribing information is available upon request



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Benefits of therapeutic clays  
in medicine

THE POWER OF  
**CLAY**

## THERAPEUTIC CLAYS IN GASTROENTEROLOGY

**FOCUS** In acute diarrhoea, clay administered orally showed a beneficial effect<sup>6,7</sup>

### IN CHILDREN, IN COMBINATION WITH A REHYDRATION SOLUTION:<sup>6</sup>

- Significant reduction in the duration of diarrhoea:  
- 1 day (vs placebo,  $p < 0.001$ )
- Significant reduction in stool frequency / day (vs placebo,  $p < 0.05$ )
- Improved stool consistency (vs placebo,  $p < 0.05$ )

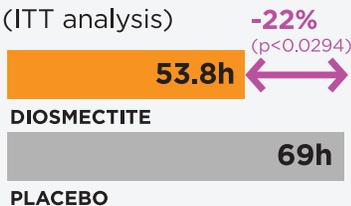
#### Methodology:<sup>6</sup>

- National, prospective, randomised, case-controlled study, including 804 children aged 3 months to 5 years\* with mild to moderate acute gastroenteritis.
- Purpose: Evaluation of the efficacy and tolerability of diosmectite in the treatment of acute diarrhoea in children.
- Intervention: oral rehydration solution alone ( $n=398$ ) or diosmectite + oral rehydration solution ( $n=406$ ).

### IN ADULTS:<sup>7</sup>

- Significant reduction in the duration of an episode:

Median time to recovery  
(ITT analysis)



#### Methodology:<sup>7</sup>

- Multi-centre randomised double-blind, placebo-controlled trial including 346 patients with an acute diarrhoea episode.
- Purpose: Evaluation of the efficacy and tolerability of diosmectite in the treatment of acute diarrhoea in adults
- Intervention: Diosmectite 1g ( $n=173$ ) or placebo ( $n=173$ ) 3 times/day, with a maximum of 6 times/day from D1 to D4.
- Safety: In total, 6 AEs in 6 patients (3.5%) of the diosmectite group and 6 AEs in 5 patients (2.9%) of the placebo group; in both groups, the most frequently reported AEs were gastrointestinal disorders.

#### Reference:

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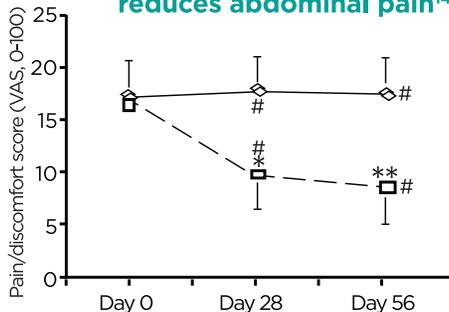
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### FOCUS Chronic diarrhoea and abdominal pain in adults

- Randomised double-blind studies, variable methodological quality studies, control vs placebo or comparator (loperamide, probiotics, bismuth nitrate) conducted in adults with chronic functional diarrhoea caused by irritable bowel syndrome<sup>12-17</sup>
- Clay studied: Diosmectite
- Main assessment criteria:
  - Overall score for irritable bowel syndrome
  - Reduction in diarrhoea: number and consistency of stools
  - Decreased abdominal pain
  - Decreased discomfort
- Tolerance: Main adverse events reported: constipation, nausea, vomiting

### FOCUS In adults with chronic diarrhoea, clay administered orally reduces abdominal pain<sup>14</sup>



- \* Significant change from baseline,  $P < 0,01$
- # Group difference within the same visit,  $P < 0,05$
- Dioctahedral smectite
- ◇ Placebo

- Significant reduction of abdominal pain:<sup>14</sup>
  - D28: 41% reduction (vs placebo,  $p < 0.05$ )
  - D56: 53% reduction (vs placebo,  $p < 0.05$ )

#### Methodology:<sup>14</sup>

- Phase III, randomised, double-blind, placebo-controlled trial including 104 patients with chronic diarrhoea (D-IBS Rome II criteria)
- Purpose: Assessment of the efficacy and safety of diosmectite 1g in the treatment of chronic diarrhoea in adults
- Intervention: 3 daily sachets of placebo (n=52) or diosmectite 1g (n=52) for 8 weeks
- Safety: Neither serious drug related adverse effects nor death were reported.

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## Mechanisms of action involved

- Gastric and intestinal protective effects due to:<sup>8-11</sup>
  - Adsorption of pathogens and toxins
  - Coating power and protective barrier
  - Anti-inflammatory effect
  - Reduced intestinal permeability



AMONG THE GASTROINTESTINAL EFFECTS OF CLAYS, THE BENEFITS ON ACUTE AND CHRONIC DIARRHOEA HAVE BEEN THE **MOST STUDIED AND ARE BASED ON THE NATURAL PROPERTIES OF CLAYS.**

### Reference:

5. Dupont C et al. Clin Gastroenterol Hepatol 2009;7:456-62
6. Guarino A, et al. Smectite in the Treatment of Acute Diarrhea: A Nationwide Randomized Controlled Study of the Italian Society of Pediatric Gastroenterology and Hepatology (SIGEP) in Collaboration With Primary Care Pediatricians. JPGN 2001; 32:71-75.
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