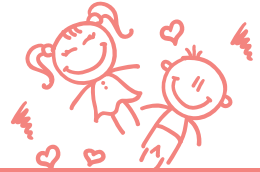


# Dioclear<sup>+</sup>

MEDICAL DEVICE CONTAINING DIOSMECTITE

FOR THE TREATMENT OF ACUTE  
AND CHRONIC DIARRHOEA



## 1. Identification, composition and purpose of the MD

### 1.1 Description and instructions for use.

DIOCLEAR is a disposable powder medical device for extemporaneous oral suspension, indicated for the oral treatment of acute and chronic diarrhoea and painful symptoms related to gastrointestinal disorders.

### 1.2 Mechanism of action

Diosmectite is a natural clay characterized by a structure of fine overlapping crystalline lamellae which gives a high absorbing power, to make it capable of incorporating the liquids present in the intestinal lumen, increasing stool consistency and slowing expulsion. The absorbance power of diosmectite also allows DIOCLEAR to interact with the glycoproteins of the mucous layer covering the gastroduodenal wall, changing their physical characteristics so to form a protective gel against acid hypersecretion and gastrolesive substances.

## 2. Composition

One sachet of DIOCLEAR contains:  
Diosmectite 3g

Excipients: orange flavour, citric acid, silicon dioxide, acesulfame K, sucralose

## 3. Pack size

The pack contains 10 disposable sachets of 3.25g each.

## 4. Instructions for use

**Adults:** 1 sachet 3 times per day.

**Children of age 6-18 years:** 1 sachet 2-3 times per day.

**Children of age 2-6 years:** 1 sachet 1-2 times per day.

Before using the product in children, it is advisable to seek medical advice.

Each sachet shall be used only once after its opening. Dissolve the content of each sachet in a glass of water or other liquid.

For children, the contents of the sachet can be suspended in the bottle feeder in 50ml of water or mixed with any other beverage, and divided into 2-3 doses throughout the day. It is also possible to dissolve DIOCLEAR in semisolid feedings.

To obtain a homogeneous suspension, pour powder slowly into the liquid and mix well.

It is advisable to consume Dioclear between meals.

In children, the treatment of acute and chronic

diarrhoea must be accompanied by the early administration of an oral rehydration solution (ORS) to avoid dehydration.

In adults, if necessary, it is advisable to consume ORS during the treatment with DIOCLEAR to assure a proper rehydration.

## 5. Known side effects

There are no known side effects related to the long-term usage of Dioclear. In case of overdose, constipation can occur. In case of occurrence of side effects different from those listed, contact your doctor.

Dioclear is a medical device for the creation of an oral suspension, useful as adjuvant in the oral treatment of acute and chronic diarrhoea.



### 6. Warning and precautions

- Do not use Dioclear for more than 10 consecutive days. If the symptoms persist, you should consult your doctor.
- Keep Dioclear out of the reach of children.
- In children, if diarrhoea persists for longer than 3 days seek medical advice.
- Do not take Dioclear when lying down.
- Do not use Dioclear after the expiration date on the box and the sachet.
- Do not use if package is damaged.
- Each sachet is disposable and should be opened only immediately before taking. Do not reuse sachets partially used, as such usage mode may involve risks as ineffective solution or contamination of the product.
- Do not exceed the recommended dose, in case of adverse effects (constipation, intestinal pain, flatulence) suspend use and consult your doctor.
- In case of unexpected side effects other than those listed, consult a doctor.
- Do not use in presence of gastric or intestinal lesions, or in case of chronic constipation, or intestinal irritation or intestinal blockage.
- Dioclear contains aluminium resulting from diosmectite. If you are using other products or drugs containing diosmectite, clay or aluminium compound consult your doctor before taking Dioclear.
- Do not take Dioclear when using other devices or oral medicines. The absorbing effect of diosmectite may adversely affect their efficacy. Consult your doctor before taking Dioclear in case of concomitant drug therapies.

### 7. Contraindications and limitation of use

Do not use Dioclear in children under 2 years. Do not consume Dioclear in case of known hypersensitivity to the components of the medical device. Do not use the product in case of pregnancy or breastfeeding.

### 8. Storage

DIOCLEAR should not be used after the expiry date indicated on the package. Store the product at room temperature (< 25°C), avoid exposure to direct light sources, heat and excessive humidity; avoid contact with water.

The expiration date on the package refers to the product in unopened packages and properly stored.

### 9. Disposal

Do not dispose in any case the product or its packaging into the environment. Dispose the device according to regulations imposed by Local manager.

 S.I.L.T. Srl  
Via Ariosto, 50/60  
20090 Trezzano sul Naviglio (MI)  
Italy

Distributed by:

 CF Pharma<sup>+</sup>

CF Pharma Ireland Ltd  
Unit 73B, Hebron Ind Est,  
Kilkenny, Ireland

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