



## Dioclear

Contains Diosmectite

For use in Acute and Chronic Diarrhoea

### 1. Identification, composition and purpose of **DIOCLEAR**

#### 1.1 Description and instructions for use.

**DIOCLEAR** is a disposable powder indicated for the oral use in acute and chronic diarrhoea.

#### 1.2 Mechanism of action

Diosmectite is a natural clay with high absorbent capacity, allowing absorption of the liquids present in the intestinal lumen, increasing stool consistency and slowing expulsion of stools. Diosmectite also plays a role in forming a protective barrier in the intestines.

### 2. Composition

One sachet of **DIOCLEAR** contains:

Diosmectite 3 g

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

### 3. Pack size

The pack contains 10 disposable sachets of 3,25 g each.

### 4. Instructions for use

**Adults:** 1 sachet in 100 ml of liquid 3 times per day.

**Children > 6 years:** 2-3 sachets per day.

**Children >1 year:** 1-2 sachets per day.

Each sachet shall be used only once after it is opened. Dissolve the content of each sachet in a glass of water.

Before using **DIOCLEAR** in children it is advisable to seek medical advice.

For children, the contents of the sachet can be suspended in the bottle feeder in 50 ml of water and divided into 2-3 doses throughout the day. It is also possible to dissolve **DIOCLEAR** in semi-solid feedings.

To obtain a smooth 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 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

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occurrence of side-effects different from those listed, contact your healthcare professional.

### 6. Warnings and precautions

- **Keep DIOCLEAR out of the reach of children.**
- Do not use for more than 3 consecutive days in acute diarrhoea. If the symptoms persist, you should consult your healthcare professional.
- Please consult with your healthcare professional if you are **pregnant** or **breastfeeding**.
- 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 use. Do not reuse partially used sachets, as this might pose a risk to get an ineffective solution or contaminate **DIOCLEAR**.
- Do not exceed the recommended dose, in case of adverse effects, i.e. constipation, intestinal pain and flatulence. Discontinue use and consult your healthcare professional.
- In case of unexpected side-effects other than those listed, consult a healthcare professional.
- Do not use if gastric or intestinal lesions are present, or in the case of chronic constipation, intestinal irritation or intestinal blockage.
- **DIOCLEAR** contains aluminum resulting from diosmectite. If you are using other products containing diosmectite clay or aluminum compound consult your healthcare professional before taking **DIOCLEAR**.

- Do not take **DIOCLEAR** when using any oral medicines as the absorbance of diosmectite may adversely affect the efficacy of other product. Consult your doctor or pharmacist before taking **DIOCLEAR** when taking co-administered products.

### 7. Contraindications and limitation of use

Do not take **DIOCLEAR** if you are hypersensitive to any of the ingredients in **DIOCLEAR**. **DIOCLEAR** is not for use in infants under 12 months.

### 8. Storage instructions:

**DIOCLEAR** should not be used after the expiry date indicated on the package. Store the product in dry conditions at or below 25 °C. Avoid exposure to direct sunlight, heat and excessive humidity.

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

### 9. Disposal

Return all unused product to your healthcare professional. Do not dispose of unused product in drains or sewerage systems (e.g. toilets) or into the environment.

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Dioclear creates an oral suspension, useful as adjuvant in the management of diarrhoea.