

## Diosmectite powder

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

#### 1.1 Description and instructions for use.

TAMMEX FAMILY is a disposable powder medical device for ex-temporaneous oral suspension, indicated for the oral treatment of acute diarrhoea and painful symptoms related to gastrointestinal disorders.

#### 1.2 Mechanism of action

The 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 the TAMMEX FAMILY to interact with the glycoproteins of the mucous layer covering the gastroduodenal wall, changing their physical characteristics to form a protective gel against acid hypersecretion and gastrolesive substances.

### 2. Composition

One sachet of TAMMEX FAMILY 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.

**Babies >1 year:** 1-2 sachet per day.

**Babies < 1 year:** 1 sachet per day and after consulting the paediatrician.

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 babies, 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 the TAMMEX FAMILY in semisolid feedings.

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

It is advisable to consume the TAMMEX FAMILY between meals.

In children and infants, the treatment of acute 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 TAMMEX FAMILY to assure a proper rehydration.

## 5. Known side effects

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

## 6. Warning and precautions

- Keep the device out of the reach of children.
- Do not use for more than 10 consecutive days. If the symptoms persist, you should consult your doctor.
- Do not take TAMMEX FAMILY when lying down.
- Do not use the device 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 re-use bags 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.
- Do not take TAMMEX FAMILY when using other devices or oral medicines: the absorbing effect of diosmectite may adversely affect their efficacy. Consult your physician before taking TAMMEX FAMILY in case of concomitant drug therapies.

## 7. Contraindications and limitation of use

Do not take the device if you are allergic to any of the components in TAMMEX FAMILY. Please consult with your doctor if you are pregnant or breastfeeding.

## 8. Conservation

TAMMEX FAMILY should not be used after the expiry date indicated on the package.

Store the product at room temperature (max 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

Dispose the device according to regulations imposed by your local authority.



Unit 619B, IDA Industrial Estate  
Northern Extension  
Waterford, Ireland.

**WALMARK®**

Distributor: Walmark®  
Oldřichovice 44, 73961 Trinec  
Czech Republic

Licensee: DH-norm s.r.o.



Last Revision: June 2013