# PROFESSIONAL INFORMATION

## SCHEDULING STATUS

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## 1. NAME OF THE MEDICINE

**IMPILO DIARRHOEA MIXTURE,** 1,875 g & 65,0 mg, suspension

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Kaolin (Light) 1,875 g

Pectin (Apple) 65,0 mg

Ethanol (96 %) 0,44 % *v/v*

Preservatives:

Methyl hydroxybenzoate 0,20 % *m/v*

Propyl hydroxybenzoate 0,02 % *m/v*

Contains sweetener: Saccharin sodium 5,50 mg

Sugar free

For a full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension

A smooth off-white suspension

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

IMPILO DIARRHOEA MIXTURE, as adjunct to rest, fluids and appropriate diet, is indicated in the symptomatic treatment of mild to moderately acute diarrhoea.

### 4.2 Posology and method of administration

**Posology**

SHAKE BOTTLE BEFORE USE

The dose should be taken in water 3 to 4 times daily

Children: 3 to under 6 years: 1,5 to 3 medicine measures (7,5 to 15 ml)

6 to under 12 years: 3 to 6 medicine measures (15 to 30 ml)

12 years and over: 6 medicine measures (30 ml)

Adults and adolescents: 6 to 12 medicine measures (30 to 60 ml)

NOT FOR USE IN CHILDREN UNDER THREE YEARS OF AGE.

As a consequence of diarrhoea, the patient may become dehydrated. If the symptoms persist for more than 48 hours, or the condition of the patient deteriorates, use of the product must be discontinued and a doctor must be consulted. Hydration may be maintained by the administration of adequate fluids and or electrolytes.

Do not exceed the recommended dosage unless on the advice and under the supervision of a doctor.

**Method of administration**

For oral use only.

### 4.3 Contraindications

- Hypersensitivity to any of the ingredients,
- intestinal obstruction,
- patients with chronic ulceration of the gastrointestinal tract or who have undergone colostomies.
- IMPILO DIARRHOEA MIXTURE should not be given to children under the age of 3 years (see Section 4.2).

### 4.4 Special warnings and precautions for use

Caution is recommended when using IMPILO DIARRHOEA MIXTURE by children and the elderly.

Due to the risk of electrolyte and fluid loss, adequate hydration should be ensured.

The absorption of other medicines, notably digoxin, from the gastrointestinal tract may be reduced if taken concomitantly.

Other medicines should therefore not be taken at the same time as IMPILO DIARRHOEA MIXTURE (see Section 4.5).

A doctor should be consulted if the symptoms worsen or do not improve after 48 hours.

### 4.5 Interaction with other medicines and other forms of interaction

Concurrent use of IMPILO DIARRHOEA MIXTURE with anticholinergics or medicines with anticholinergic activity, antidyskinetics, digoxin, clindamycin and lincomycin, loxapine, phenothiazines or thioxanthenes may impair absorption of these medicines when administered orally which can result in decreased therapeutic efficacy.

Coadministration of Dolutegravir with IMPILO DIARRHOEA MIXTURE may decrease the bioavailability of dolutegravir.

It is recommended that IMPILO DIARRHOEA MIXTURE is administered at least 2 to 3 hours before or after other oral medicines.

**4.6 Fertility, pregnancy and lactation**

The safety of this preparation in pregnancy and lactation has not been established.

No fertility data available.

**4.7 Effects on ability to drive and use machines**

No effect is expected on the ability to drive and use machines.

**4.8 Undesirable effects**

The following side effects may occur:

**Gastrointestinal disorders**

*Frequency unknown:* Constipation.

This side effect may be mild and transient but may lead to faecal impaction.

**Reporting of suspected adverse reactions**

Reporting of suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRAvia the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

### 4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Treatment is supportive and symptomatic.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antidiarrhoeals, intestinal anti-inflammatory/anti-infective agents

ATC code: A07BC

Kaolin and pectin have absorbent properties.

### 5.2 Pharmacokinetic properties

*Absorption*

Not absorbed (up to 90 % of pectin is decomposed in the gastrointestinal tract).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Chloroform

Creamy Toffee F1744

Ethanol (96 %)

Methyl hydroxybenzoate

Propyl hydroxybenzoate

Purified water

Saccharin sodium

Sodium citrate (trisodium)

Vanillin

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store in a cool place, at or below 25 °C.

Keep bottle tightly closed.

### 6.5 Nature and contents of container

100 ml clear PVC bottles with white caps packed in an outer carton.

### 6.6 Special precautions for disposal

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Avid Brands S.A. (Pty) Ltd

Suite 9, Hillcrest Office Park

2 Old Main Road

Hillcrest

3610

## 8. REGISTRATION NUMBER

32/11.9/0359

## 9. DATE OF FIRST AUTHORISATION

14 March 2001

## 10. DATE OF REVISION OF THE TEXT

25 January 2023