SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FRIDIAL® Children's oral solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Prifinium bromide..... 250 mg

Excipient with known effect: sucrose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution, 50 ml bottle with a dosing pipette.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Vomiting:

- Common of the infant or child
- Acute gastroenteritis
- Accompanying febrile states
- Due to drug intolerance

Abdominal pain syndromes:

- Functional bowel disorders with or without bowel movement problems, with or without bloating.

Diarrhea.

As a complement to etiological treatments for organic digestive diseases.

4.2. Posology and method of administration

Posology

As prescribed by a doctor. On average, ½ dose (0.2 ml) per kg of body weight per day, most often divided into 3 doses per day.

Dose distribution table:

Weight (kg)	4-6	6-8	8-10	10-12	12-14	14-16	16-18	18-20	20-22	22-24	24-26
Morning	1	1	1	2	2	2	3	3	3	4	4
Noon	-	1	1	1	2	2	2	3	3	3	4
Evening	1	1	2	2	2	3	3	3	4	4	4

26-28	28-30	30-32	32-34	34-36	36-38	38-40	40-42	etc
4	5	5	5	6	6	6	7	
4	4	5	5	5	6	6	6	
5	5	5	6	6	6	7	7	

Method of administration

Oral route
Unscrew the cap
Fill the dosing pipette up to the prescribed number of doses.
Empty the contents preferably into water or any other beverage.
The bottle must be closed after each use.

4.3. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

- Intraocular hypertension.
- Lesions of the lower urinary tract that can lead to urinary retention.

4.4. Special warnings and precautions for use

Due to the presence of sucrose, this medication is contraindicated in cases of fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase- isomaltase deficiency.

4.5. Interactions with other medicinal products and other forms of interaction

Although it has no central nervous system action, there is a possibility that Fridial for children may potentiate the action of hypnotics.

4.6. Fertility, pregnancy and breastfeeding

There are currently no relevant or sufficient data to assess a possible malformative or fetotoxic effect of prifinium bromide administered during pregnancy.

Therefore, as a precaution, it is best not to use prifinium bromide during pregnancy.

4.7. Effects on the ability has to drive of the vehicles And has to use of the machines

No particular requirements.

4.8. Undesirable effects

A sensation of dry mouth may occur. This should not, in principle, lead to stopping treatment; the child's thirst should normally be satisfactory.

Very rare cases of drowsiness have been observed. These resolved with a simple dose reduction.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions is important. It allows for continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals must report any suspected adverse reactions according to the procedures defined in the Therapeutic Use and Data Collection Protocol (PUT RD).

4.9. Overdose

Administering doses ten times higher than the antimuscarinic doses used in therapy produces ganglionic effects ; if these doses are one hundred times higher, a curarizing effect is observed, and in the event of massive absorption, respiratory support must be implemented and eserine administered.

5. PHARMACOLOGICAL PROPERTIES

5.1. Properties pharmacodynamics

Pharmacotherapeutic class: MEDICATIONS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, code ATC : A03AB18 .

Anticholinergic acting preferentially on muscarinic receptors in the digestive tract. Corrects hypersecretion of hydrochloric acid , gastric acid , and pancreatic acid.

Corrects hypermotility of the digestive tract. Administered orally, it respects gastric emptying and allows the basic motility activity of the digestive smooth muscle.

5.2. Pharmacokinetic properties

Absorption

Absorbed via the digestive tract

Distribution

Prifinium bromide is distributed preferentially in the digestive tract.

Elimination

Prifinium bromide is eliminated primarily via the biliary route and in the secretions of the digestive tract.

5.3. Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of the excipients

Ammonium glycyrrhizate , sodium methylparaben , sucrose, dilute hydrochloric acid R2, purified water

6.2. Incompatibilities

Without object.

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store at a temperature below 25°C.

6.5. Nature and contents of container

50ml amber glass bottle with dosing pipette.

6.6. Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

7. HOLDER AND MANUFACTURERS

Holder and operator of the export marketing authorization

FRILAB SA

17, rue des Pierres du Niton

1207 Geneva SWITZERLAND

Manufacturer

TERIAK Laboratories, Industrial Zone 1111, Djebel Ouest, Zaghouan, Tunisia

8. DATE OF REVISION OF THE TEXT

January 24, 2023

9. DOSIMETRY

Without object.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List II.