SUMMARY OF PRODUCT CHARACTERISTICS

1- DENOMINATION

FRIDIAL® Child Oral solution.

2- Qualitative and quantitative composition

Active ingredient
prifinium bromide. ..... 250 mg
excipients
ammonium glycyrrhizinate ..... 50 mg
sodium Méthylparahydroxybenzoate. ..... 50 mg
Sucrose…….. 15 g
dilute hydrochloric acid R2 .... qs pH 7.0
Purified water…… qs 50 mL

3- PHARMACEUTICAL FORM

oral solution, 50 ml vial (with graduated pipette to 0.4 ml).

4- CLINICAL

4.1 Therapeutic Indications

Spasmodic Functional impairment of the digestive axis of infants and children in particular; vomiting, abdominal pain syndromes.
Further treatment of the etiological therapeutic organic digestive diseases.

4.2 Dosage and method of administration

Dosage:

0.4 ml (one pipette filled to the red line) by 2 kg of weight per day (2 mg / 2kg / day) divided into 3 doses with a little water.

Fill the pipette to the mark according to the weight of the child:

Weight (kg)	4-6	6-8	8-10	10-12	12-14	14-16	16-18	18-20	20-22	22-24	24-26	26-28	28-30	30-32	32-34	34-36	36-38	38-40	40-42	etc.
Morning	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	
Midday	-	1	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	
Evening	1	1	2	2	2	3	3	3	4	4	4	5	5	5	6	6	6	7	7	

Administration mode :

orally.

The solution can be drunk pure or diluted in a small amount of beverage (eg water, milk, fruit juice).

4.3 Contraindications

- intraocular pressure.
- Lesions of the lower urinary tract exposing to urinary retention.

4.4 Special warnings and precautions for use

Due to the presence of sucrose, this medicine is against-indicated in case of fructose intolerance, malabsorption of glucose and galactose or sucrase-isomaltase

4.5 Interaction with other drugs and other forms of interaction

Although pharmacologically devoid of central action, there is a possibility that Fridial child potentiates the action of hypnotics

4.6 Pregnancy and lactation

There is currently no relevant or sufficient data to evaluate a possible harmful effect of bromide prifinium administered during pregnancy. Consequently, as a precautionary measure, it is preferable not to use the prifinium bromide for the pregnancy

4.7 Driving and operating machinery

No special requirements

4.8 Undesirable effects

- A feeling of dry mouth can occur. This phenomenon should not in cause the discontinuation of the treatment
- Very rare cases of drowsiness were observed. They yielded to a simple dose reduction

4.9 Overdose

The administration of ten times higher doses than doses used in antimuscarinic therapy generates gangliophégiques effects; if these doses are a hundred times stronger, there is a neuromuscular blocking effect and at massive absorption, we must implement a respiratory support and administer eserine.

5- PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Anticholinergic preferably acting at muscarinic receptors in the gastrointestinal tract. Corrects chlorhydropeptique hypersecretion, gastrin, pancreatic.
Corrects hypermotility of the gastrointestinal tract. Administered orally, it respects gastric emptying and allows elementary motor activity of the digestive smooth fiber.

5.2 Pharmacokinetic properties

Absorbed from the gastrointestinal tract, prifinium bromide preferentially distributes in the gastrointestinal tract. It is eliminated mainly via the bile and gut secretions.

The massive or parenteral administration can lead to action on other devices such as the eye, heart, salivary glands.

6- PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Not applicable.

6.2 Shelf life

2 years.

6.3 Special precautions for storage

Store at a temperature below 25 ° C.

6.4 Nature and content of container

Brown bottle with pipette dropper

6.5 Operating instructions, instructions for handling

The stillgouttes cap must be filled to the red line gauge.
The content is preferably emptied into the water or other beverage.
The amount of Fridial® administered depends on the weight of the child.
The bottle should be resealed after use.

7- PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

50 ml of oral solution in a brown glass bottle type III.

8- CONDITIONS OF PRESCRIPTION AND DELIVERY

List II.

9- OPERATOR AND MANUFACTURER

Owner and Operator abroad:
FRILAB SA
17, rue des Pierres du Niton
1207 Genève SWITZERLAND

Made by Laboratoires TERIAK
ZI Jebel Ouest Tunisia