FRIDIAL® 30 mg
Coated tablets

Summary of product characteristics

1- DENOMINATION

FRIDIAL 30 mg film-coated tablets

2- Qualitative and quantitative composition

Core	
Bromide prifinium	30.00
Corn starch	18.00
lactose monohydrate	55.20
croscarmellose	8.40
Colloidal anhydrous silica	2.40
povidone K30	4.80
Magnesium Stearate	1.20
kernel weight	***120.000 mg***

Coating	
Opadry II pink 85F2400321)	3.60 mg
total mass for a film-coated tablet	***123.60 mg***

[1)] Qualitative composition of the Opadry II pink 85F240032: polyvinyl alcohol - Macrogol 4000 - titanium dioxide, talc, aluminum lake of erythrosine, indigo carmine aluminum lake of

3- PHARMACEUTICAL FORM

Film-coated tablet
Box of 10 or 20

4- CLINICAL

4.1 Therapeutic Indications

This drug is indicated in adults for the treatment of:

- Pain due to spasm and hypermotility of the gastrointestinal tract: gastritis, peptic ulcer, enteritis, post-gastrectomy syndrome colitis, irritable bowel syndrome.
- Pain due to spasms and dyskinesia biliary tract: cholecystitis, cholelithiasis. Pain due to pancreatitis.
- Pain due to spasms of the urinary tract: urinary stones, bladder tenesmus, cystitis and pyelitis.
- Premedication for endoscopic gastric u gastrointestinal radiography.
- Dysmenorrhea and vomiting.

4.2 Dosage and method of administration

adults	30-60 mg three times a day. In acute colic, 90 mg may be administered as a single dose

Administration mode
The tablets are to be administered orally. The tablets can be taken with or between meals

4.3 Contraindications

Anticholinergics are cons-indicated in patients with prostatic hypertrophy or glaucoma.

4.4 Special warnings and precautions for use

Anticholinergics generally increase eye pressure. In patients with prostatic hypertrophy, anticholinergics can weaken the maximum bladder pressure, increase its volume and may occasionally aggravate dysuria

4.5 Interaction with other drugs and other forms of interaction

Although pharmacologically devoid of central action, there is a possibility that this drug potentiates the action of hypnotics

4.6 Pregnancy and lactation

No special requirements

4.7 Driving and operating machinery

No special requirements

4.8 Undesirable effects

Adverse effects are rare and include: dry mouth, constipation, blurred eye accommodation. However, these symptoms disappear after reduction or discontinuation.

4.9 Overdose

Empty the stomach by aspiration or washing. A purgative salt should be administered to induce peristalsis. The phisostigmine salicylates (1 to 2 mg) should be injected intramuscular, intravenous or subcutaneous to control central and anti-cholinergic devices.

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 the gastric emptying and allows elementary motor activity of the digestive smooth fiber

5.2 pharmacokinetic properties

1. *Absorption*
   Low intestinal absorption: only 15 to 25% of the administered dose per os. This low resorption can be explained by the formation of a non-absorbable complex between the positive charge of the quaternary ammonium and intestinal mucus.
2. *Repartition*
   Does not cross the blood-brain barrier (property due to the quaternary ammonium).
   The location was demonstrated at muscarinic receptors in the gut.
3. *Elimination*
   kidney: Elimination without transformation of approximately 50% in 48 hours of a dose of 7.5 mg subcutaneously, 70% are excreted in the first 4 hours following the injection. Only

2 to 4% of a 60 mg oral or rectal administration, of which 70% are excreted in 8 hours after taking: bile duct, fast elimination, fecal route

PHARMACEUTICAL DATA

6.1 Incompatibilities

Not applicable

6.2 Shelf life

2 years

6.3 Special precautions for storage

Stored in a dry place between 15-25 ° C

6.4 Nature and content of container

PVC / PVDC / Aluminum box of 10 or 20 tablets

6.5 Operating instructions, instructions for handling

No special requirements

6- PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

Blisters in blister pack (PVC / PVDC / Aluminum) 10 or 20 tablets

7- CONDITIONS OF PRESCRIPTION AND DELIVERY

list II

8- MANUFACTURER AND OPERATOR MARKETING MARKETING AUTHORIZATION

Manufactured by Laboratoires TERIAK, Cheylus- 1111 ZAGHOUAN
Operator: Laboratoires FRILAB SA, 17, rue des Pierres du Niton, 1207 Genève, Switzerland