# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**FRIDIAL 30 mg film-coated tablets**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Prifinium bromide.....30.00 mg

For one tablet
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablets

Box of 10 or 20

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

This medication is indicated in adults for the treatment of:

- Pain due to spasms and hypermotility of the gastrointestinal tract: Gastritis, gastroduodenal ulcer, enteritis, colitis, post-gastrectomy syndrome, irritable bowel syndrome .
- Pain due to spasms and dyskinesias of the bile ducts: cholecystitis, cholelithiasis . Pain due to pancreatitis.
- Pain due to spasms of the urinary tract : urinary lithiasis, bladder tenesmus, cystitis and pyelitis.
- Premedication for a gastric endoscopy or gastrointestinal radiography.
- Dysmenorrhea and vomiting.

### 4.2. Posology and method of administration

**Posology**

Adults: 30-60 mg 3 times a day. In acute colic, 90 mg may be administered as a single dose.

**Method of administration**

The tablets should be taken orally. The tablets can be taken with or between meals.

### 4.3. Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
Anticholinergics are contraindicated in patients with prostatic hypertrophy or glaucoma.

### 4.4. Special warnings and precautions for use

Anticholinergics generally increase intraocular pressure. In patients with prostatic hypertrophy, anticholinergics may lower maximum bladder pressure, increase bladder volume, and may occasionally worsen dysuria .

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

Although FRIDIAL 30 mg film-coated tablets are pharmacologically devoid of central action, there is a possibility that this medication may potentiate the action of hypnotics.

### 4.6. Fertility, pregnancy and breastfeeding

No special requirements

### 4.7. Effects on the ability to drive vehicles and use machinery

FRIDIAL 30 mg film-coated tablets has no effect or a negligible effect.

### 4.8. Undesirable effects

Undesirable effects are rare and include dry mouth, constipation, and blurred vision. However, these symptoms

disappear when the treatment is reduced or stopped.

**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

Empty the stomach by aspiration or lavage. A purgative salt should be administered to induce peristalsis. Physostigmine salicylates (1 to 2 mg) should be injected intramuscularly, intravenously, or subcutaneously to control the central and peripheral effects of anticholinergics .

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1. Pharmacodynamic properties

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

**Mechanism of action**

Anticholinergic acting preferentially on muscarinic receptors in the digestive tract. Corrects hydrochloride, gastrin, and pancreatic hypersecretion.

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

## 5.2. Pharmacokinetic properties

**Absorption**

Low intestinal absorption: only 15 to 25% of the orally administered dose.

This low absorption can be explained by the formation of a non-absorbable complex between the positive charge of quaternary ammonium and intestinal mucus.

**Distribution**

Does not cross the blood-brain barrier (property due to quaternary ammonium).

The localization was reportedly demonstrated at the level of muscarinic receptors in the digestive tract.

**Elimination**

Renal route:

Elimination without transformation of approximately 50% within 48 hours of a subcutaneous dose of 7.5 mg, of which 70% is excreted within the first 4 hours following injection.

Only 2 to 4% of a 60 mg oral or rectal dose, of which 70% is excreted within 8 hours of administration:

Biliary tract.

Rapid elimination.

Fecal route.

## 5.3. Preclinical safety data

Not applicable

# 6. PHARMACEUTICAL PARTICULARS

## 6.1. List of the excipients

Core : Corn starch, Lactose monohydrate , Croscarmellose sodium, Colloidal anhydrous silica, Povidone K30, Magnesium stearate

Film coating : Opadry II pink 85F240032 (Qualitative composition: polyvinyl alcohol – macrogol 4000 – titanium dioxide, talc, erythrosine aluminum lake , indigo carmine aluminum lake)

## 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

PVC/PVDC/Aluminium box of 10 or 20 tablets

### 6.6. Special precautions for disposal and handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

## 7. OPERATORS AND MANUFACTURERS

**Holder and operator of the marketing authorization**

FRILAB Laboratories 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

July 28, 2022

## 9. DOSIMETRY

Without object.

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## CONDITIONS FOR PRESCRIPTION AND DISPENSING

List II