SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FLOROVEL 160 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Phloroglucinol ..... 160 mg

For a coated tablet.

Excipients with known effects : Lactose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Symptomatic treatment of pain related to functional disorders of the digestive tract and biliary tract.
- Treatment of acute spasmodic and painful manifestations of the urinary tract: renal colic.
- Symptomatic treatment of painful spasmodic manifestations in gynecology.
- Adjuvant treatment of contractions during pregnancy in association with rest.

4.2. Posology and method of administration

FLOROVEL is a symptomatic treatment. If symptoms persist, the patient's condition should be reassessed.

Posology

In adults

The usual dosage is 1 tablet at the onset of an attack. The dose may be repeated in case of severe spasms, respecting a minimum interval of 2 hours between each dose, without exceeding 3 tablets in 24 hours.

Pediatric population

This medicine is not suitable for children.

Method of administration

Oral route.

The tablets should be swallowed with a glass of water.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Combining phloroglucinol with major analgesics such as morphine or its derivatives should be avoided due to their spasmogenic effect .

Excipient(s)

Lactose
Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary disorders) should not take this medicine.

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

Not applicable.

4.6. Pregnancy and breastfeeding

Pregnancy

Animal studies have not shown any teratogenic effects of phloroglucinol . In the absence of teratogenic effects in animals, malformations in humans are not expected. Indeed, to date, substances responsible for malformations in humans have been shown to be teratogenic in animals in well-conducted studies on two species.
In clinical practice, the relatively widespread use of phloroglucinol has not revealed any apparent risk of malformations to date. However, epidemiological studies are needed to confirm the absence of risk.
Consequently, the use of phloroglucinol during pregnancy should only be considered if clearly necessary.

Breastfeeding

In the absence of data, it is advisable to avoid using this medication while breastfeeding.

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

FLOROVEL has no or negligible effect on the ability to drive vehicles and use machines.

4.8. Undesirable effects

Organ system classes	Frequency	Side effect
Skin and subcutaneous tissue disorders (see section 4.4)		
	Frequency not known	Rash, rarely hives, itching, exceptionally angioedema, anaphylactic shock (hypotension), acute generalized exanthematous pustulosis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any adverse effects suspected unwanted substance via the FRILAB declaration form available under the tab Pharmacovigilance information from the website: www.frilab.ch

4.9. Overdose

Cases of overdose have been reported without specific symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: MUSCULOTROPIC ANTISPASMODIC, ATC code: A03AX12. (A: digestive system and metabolism) (G: genitourinary system)

Mechanism of action

Phloroglucinol and trimethylphloroglucinol have spasmolytic activity on smooth muscles and a visceral antinociceptive effect, particularly following episodes of acute pain .

5.2. Pharmacokinetic properties

Absorption

After oral administration, the peak plasma concentration is reached between 40 and 60 minutes.

Distribution

The tissue distribution of phloroglucinol is rapid and extensive.

Biotransformation

Phloroglucinol is metabolized in the liver by glucuronidation .

Elimination

Elimination occurs via the urinary tract in glucuronide conjugate form and via the biliary tract in free and conjugated form. The elimination half-life is approximately 1 hour 40 minutes.

5.3. Preclinical safety data

Non-clinical data from conventional studies of repeated-dose toxicity, genotoxicity and reproductive function revealed no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose, Microcrystalline cellulose (PH102), Sodium crosscamellose , Colloidal anhydrous silica, Magnesium stearate, Talc

Coating: MEDICOATT-Uni (SYS1022), Isopropyl alcohol, Methylene chloride.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

Store at a temperature below 30°C and away from light.

6.5. Nature and contents of container

This medicine comes in the form of film-coated tablets. Box of 10 film-coated 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. OPERATOR

FRILAB SA
17, rue des Pierres du Niton
1207 Geneva
SWISS

8. MANUFACTURER

Helios Pharmaceuticals Pvt. Ltd.
Village: Malpur , PO Bhud-173205
Tehsil: Nalagarh , Dist : Salan, HP, India

9. DATE OF REVISION OF THE TEXT

December 2024

10. DOSIMETRY

Not applicable

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List I