## 1. NAME OF THE MEDICINAL PRODUCT

Phloroglucinol ELC 80 mg orodispersible tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains 80 mg phloroglucinol dihydrate.

Excipients with known effect
Each tablet contains 182.45 mg lactose monohydrate and 2 mg aspartame.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Orodispersible tablet. White to off-white, round, uncoated tablets plain on both sides.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

- Symptomatic treatment of pain associated with functional gastrointestinal tract and bile duct disorders.
- Treatment of acute painful spasmodic urinary tract problems: renal colic.
- Symptomatic treatment of painful spasmodic gynaecological problems.
- Adjuvant treatment of contractions during pregnancy in combination with rest.

### 4.2 Posology and method of administration

Posology

*Adults*

The dose is 2 tablets to be taken when the pain occurs, to be repeated if there are severe spasms with a minimum interval of 2 hours between each dose without exceeding 6 tablets per 24 hours.

The active substance is a symptomatic treatment. In case of persistence of symptoms, the treatment should be reassessed.

*Paediatric population*

In children over 2 years, the dose is 1 tablet to be taken when the pain occurs, to be repeated if there are severe spasms with a minimum interval of 2 hours between the previous dose without exceeding 2 tablets per 24 hours.

The efficacy in children under 2 years of age has not been established.

Method of administration

Oral use.

In adults, the tablets may be taken by dissolving them under the tongue without water or after dissolving them in water.

In children, they must be dissolved in a glass of water before being taken. The reconstituted solution should be drunk immediately.

## 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- In patients with phenylketonuria as this medicinal product contains aspartame.

## 4.4 Special warnings and precautions for use

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

This medicine contains 2 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

## 4.5 Interaction with other medicinal products and other forms of interaction

Avoid combining phloroglucinol with major analgesics such as morphine or morphine derivatives as they cause spasms.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies have not demonstrated any teratogenic effects of phloroglucinol.

In the absence of teratogenic effects in animals, no malformative effects are expected in humans. To date, substances causing malformations in humans have been shown to be teratogenic in animals during well-conducted studies in two species.

In clinical practice the relatively widespread use of phloroglucinol has apparently revealed no teratogenic risk to date. However, epidemiological studies are required in order to verify the absence of this risk.

Therefore, the use of phloroglucinol should only be considered during pregnancy if necessary.

Breast-feeding

In the absence of data, it is advisable to avoid using this medicine while breast-feeding.

## 4.7 Effects on ability to drive and use machines

Phloroglucinol ELC has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

| System Organ Class | Preferred adverse effect term | Frequency |
|---|---|---|
| Skin and subcutaneous tissue disorders | Eruption, rarely urticaria, pruritus, exceptionally - Quincke's oedema, anaphylactic shock (low blood pressure), generalised acute exanthematous pustulosis | Unknown frequency |

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

## 4.9 Overdose

Cases of overdose have been reported without any specific symptomatology.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Musculotropic antispasmodic agent (A: Alimentary tract and metabolism) (G: Genitourinary system), ATC code: A03AX12

Mechanism of action

Phloroglucinol exerts spasmolytic action on the smooth muscles and an anti-nociceptive effect on the viscera, in particular during bouts of acute pain.

## 5.2 Pharmacokinetic properties

**Absorption**
After oral administration, the peak plasma level is reached between 15 and 20 minutes.

**Distribution**
The tissular distribution of the phloroglucinol is quick and important.

**Biotransformation**
The phloroglucinol is biotransformed on the liver level by glucuronic acid conjugation.

**Elimination**
The elimination is performed by urinary route as glucuronic conjugate and by biliary route free and conjugate. The half -life is about 1hour 40.

## 5.3 Preclinical safety data

Non clinical data from toxicological conventional studies upon repeated administration, genotoxicity studies and reproductive function studies did not reveal any particular risk for humans.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Povidone
Magnesium stearate
Aspartame (E 951).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years
After opening the HDPE bottle: 1 month

### 6.4 Special precautions for storage

Store below 30°C.
Blister packs: Store in the original package (blister) in order to protect from moisture.
Bottles: Keep the bottle tightly closed to protect from moisture.

### 6.5 Nature and contents of container

10, 20 or 30 tablets in (PVC/PVDC/Aluminium) blister packs.
20 tablets in container (HDPE)
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. MARKETING AUTHORISATION HOLDER

ELC GROUP s.r.o.
Pobřežní 394/12, Karlin, 18600 Prague 8
Czech Republic

## 8. MARKETING AUTHORISATION NUMBER(S)

MA 1083/00501

## 9. DATE OF FIRST AUTHORISATION/RENEWAL

First authorisation: 20/08/2019
Renewal: 12/08/2024

## 10. DATE OF REVISION OF THE TEXT

13/08/2024