

## **1.NAME OF THE MEDICINAL PRODUCT**

**Herbana**

## **2.PHARMACEUTICAL FORM**

**Hard Gelatine Capsule**

## **3.QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each hard gelatin capsule contains:

- \* **Fenugreek seed powder** 250 mg  
Standardized as: N.L.T 0.4% trigonelline.
- \* **Fennel fruit powder (bitter)** 50 mg  
Standardized as:  
Anethol: minimum 60.0 % in the essential oil.  
Essential oil: minimum 40 ml /kg (anhydrous drug)
- \* **Dill fruit powder** 50 mg  
Standardized as: Volatile oil 2-5 % [calculated as Carvone (20-60%)]
- \* **Caraway fruit powder** 150 mg  
Standardized as: N.L.T 2.5 %v/w (25 ml/kg) of essential oil. [Calculated as Carvone (40-60%)]

## **4.CLINICAL PARTICULARS**

### **4.1-Therapeutic indications:**

#### **Herbal medicine used as**

- Lactagogue as Improve lactation
- In case of bloating and flatulance

### **4.2-Posology and method of administration:**

**A- Route of administration:** Orally

**B- Recommended dose:** 2 capsules Or as directed by physician.

**C- Frequency:** 3-4 times daily.

**D- Duration:** If the symptoms persist more than two weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

### **4.3-Contraindications:**

Hypersensitivity to the active substance, to other plants of the Apiaceae (Umbelliferae) family

### **4.4-Special warnings and precautions for use:**

- The use in patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders is not recommended.
- The use in children and adolescents under 18 years of age is not recommended because of incomplete data on safety.
- Due to a possible hypoglycaemic effect of fenugreek, close monitoring of glycaemic control should be considered in patients treated for diabetes mellitus.
- To be used under medical supervision (acc. To the committee decision )
- Keep out of reach of children

#### **4.5-Interaction with other medicinal products and other forms of interaction:**

It may potentiate the effect of anticoagulant drugs

#### **4.6-Fertility, pregnancy and lactation:**

There are no or limited data from use during pregnancy  
The use should be avoided during pregnancy

#### **4.7-Effects on ability to drive and use machines:**

- No studies on the effect on the ability to drive and use machines have been performed.

#### **4.8-Undesirable effects:**

**Gastrointestinal disorders:** flatulence, diarrhoea

**Nervous system disorders:** dizziness

A single case of allergic reaction to fennel has been reported

#### **4.9-Overdose:**

High doses (between 25 g and 100 g daily of debitterized powder of fenugreek seeds divided into two equal doses) have been reported to cause minor gastrointestinal symptoms such as diarrhoea and flatulence in 4 out of 10 cases.

### **5-PHARMACOLOGICAL PROPERTIES:**

**A- Pharmacodynamic properties :** Not applicable.

**B- Pharmacokinetic properties :** Not applicable.

**C- Preclinical safety data:** Not applicable.

### **6-PHARMACEUTICAL PARTICULARS:**

#### **6.1-List of excipients**

Aerosil 200, Magnesium stearate, Gelatin, Methyl paraben, Propyl paraben, Sodium lauryl sulfate, Aerosil, Yellow iron oxide (C.I. 77492) , Brilliant blue (C.I. 42090)

#### **6.2-Shelf life**

3 years

#### **6.3-Storage conditions**

Store at temperature not exceeding 30 °C in a dry place.

#### **6.4-Nature & content of container**

Carton box containing 1,2,3,4,5 (Al/opaque PVC) strips each contains 10 capsules with inner leaflet.

#### **6.5-Special precautions for disposal and other handling**

Not applicable

#### **7-Marketing authorisation holder & contact**

Marketing Authorization Holder and Manufacturer: Pharma Cure Pharmaceutical Industries

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#### **8- Marketing authorisation number(s):**

#### **9-Date of first authorisation:**

#### **10- Date of revision of the text:**