# SUMMARY OF PRODUCT CHARACTERISTICS

## 1) NAME OF THE MEDICINAL PRODUCT

**PEPSANE, capsule**

## 2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Dimeticone ..... 300.0 mg

Guaiazulene ..... 4.0 mg

For one capsule.

Excipient with known effect: sorbitol

For the full list of excipients, see section 6.1.

## 3) PHARMACEUTICAL FORM

Capsule.

## 4) CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Symptomatic treatment of painful functional disorders during oesogastroduodenal diseases.

### 4.2. Posology and method of administration

Oral use.

Swallow 1 capsule with water when the pain occurs.

### 4.3. Contraindications

Hypersensitivity to one of the ingredients.

### 4.4. Special warnings and precautions for use

If symptoms persist or worsen, it is recommended to consult your doctor.

Due to the presence of sorbitol, patients with rare hereditary problems of fructose intolerance must not take this medicine.

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

To date, the data available do not suggest the existence of clinically significant drug interactions.

### 4.6. Pregnancy and lactation

Dimeticone can be used during pregnancy and lactation.

There are no clinical data with guaiazulene in pregnant women. However, to date, no specific malformations have been reported with this medicine.

Therefore, this medicine can be taken during pregnancy and lactation.

### 4.7. Effects on ability to drive and use machines

Not applicable.

### 4.8. Undesirable effects

Hypersensitivity reactions such as rash or pruritus have exceptionally been reported.

### 4.9. Overdose

Not applicable.

## 5) PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

**Pharmacotherapeutic group: ANTACIDS**
**(A: Digestive tract and metabolism)**

Dimeticone has an effect of digestive protective agent by forming a homogeneous protective layer lining the digestive mucosa.

### 5.2. Pharmacokinetic properties

Not available.

### 5.3. Preclinical safety data

Not available.

## 6) PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Gelatin, glycerol, sorbitol at 70 per cent (non-cristallizable), patent blue V (E131), titanium dioxide (E171).

### 6.2. Incompatibilities

Not applicable.

### 6.3. Shelf-life

Blister (PVC/aluminium): 2 years.
Blister (PVC/PE/PVDC/aluminium): 2 years.

### 6.4. Special precautions for storage

Blister (PVC/aluminium): Do not store above 25°C.
Blister (PVC/PE/PVDC/aluminium): no special storage conditions.

### 6.5. Nature and contents of container

Blister (PVC/aluminium).
Blister (PVC/PE/PVDC/aluminium).

### 6.6. Special precautions for disposal and other handling

No special requirements.

## 7) MARKETING AUTORISATION HOLDER

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75001 PARIS
Standard: Tel.: +33 (0) 1 34 80 55 80
Medical information: Tel.: +33 (0)1 34 80 72 60

## 8) MARKETING AUTHORIZATION NUMBERS

- 34009 341 110 0 6: blister(s) (PVC/Aluminium) of 20 capsules.
- 34009 343 179 8 9: blister(s) (PVC/aluminium) of 30 capsules.
- 34009 300 311 7 9: blister(s) PVC/PE/PVDC/aluminium of 20 capsules.
- 34009 300 311 8 6: blister(s) PVC/PE/PVDC/aluminium of 30 capsules.

## 9) DATE OF FIRST AUTORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 28 may 1996
Date of last renewal: 28 may 2011.

## 10) DATE OF REVISION OF THE TEXT

02 october 2015.

## 11) DOSIMETRY

Not applicable.

## 12) INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

# PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription.