# SUMMARY OF PRODUCT CHARACTERISTICS

## 1) NAME OF THE MEDICINAL PRODUCT

METEOSPASMYL, soft capsule

## 2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Alverine citrate ..... 60.00 mg

Simeticone ..... 300.00 mg

For 1 soft capsule.

For the full list of excipients, see section 6.1.

## 3) PHARMACEUTICAL FORM

Soft capsule.

Soft oblong capsule, size 6, shiny opaque white, containing a thick whitish suspension.

## 4) CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Symptomatic treatment of functional bowel disorders, especially those with bloating.

### 4.2 Posology and method of administration

For oral administration.

FOR ADULTS ONLY.

1 soft capsule 2 to 3 times daily at the beginning of meals or when in pain.

### 4.3 Contraindications

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

### 4.4 Special warnings and precautions for use

**Liver function**:

Elevations in ALT (Alanine Aminotransferase) and AST (Aspartate Aminotransferase) > twice the upper limit of normal (ULN) have been reported in patients receiving treatment with alverine/simeticone. These elevations may be associated with a concomitant elevation in total serum bilirubin (see section 4.8). In case of an elevation in hepatic aminotransferases > 3 times the ULN and even more so in the case of jaundice, treatment with alverine/simeticone should be discontinued.

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

The available to date data do not suggest the existence of clinically significant interactions.

### 4.6 Fertility, pregnancy and lactation

**Pregnancy**

*Simeticone:* No effect is expected during pregnancy with the intake of simeticone due to negligible systemic exposure.

*Alverine:* There are no exhaustive data of teratogenicity in animals. Clinically, no particular malformative or foetotoxic effect has been reported to date. However, follow-up of pregnancies exposed to alverine is insufficient to exclude any risk.

Consequently, as a precautionary measure, it is preferable to avoid the use of METEOSPASMYL during pregnancy.

**Lactation**

No effect of simeticone taken during breastfeeding is expected due to negligible systemic exposure.

There are no data on the excretion of alverine in human milk.

As a result, METEOSPASMYL should be avoided during breastfeeding.

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

METEOSPASMYL has a minor influence on the ability to drive and use machines. Adverse effects such as vertigo have been reported in some patients (see sections 4.8 and 4.9). These types of disorders may affect the ability to drive and use machines.

### 4.8 Undesirable effects

The adverse reactions listed below have been reported at frequencies corresponding to: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) and undetermined frequency (cannot be estimated on the basis of the available data).

**Hepatobiliary disorders**
Very rare: cytolytic hepatitis (see section 4.4).

**Investigation**
Undetermined frequency: elevated transaminases, alkaline phosphatase, and bilirubin.

**Skin and subcutaneous tissue disorders**
Undetermined frequency: angioedema, skin rash, urticaria, and pruritus.

**Immune system disorders**
Very rare: anaphylactic type reactions, and anaphylactic shock.

**Ear and labyrinth disorders**
Undetermined frequency: vertigo.

**Nervous system disorders**
Undetermined frequency: headache.

**Gastrointestinal disorders**
Undetermined frequency: nausea.

**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 are asked to report any suspected adverse reactions via the national reporting system: Agence Nationale de Sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance. Site internet : www.ansm.sante.fr.

### 4.9 Overdose

Cases of vertigo have been reported when a higher-than-recommended dosage is taken.

## 5) PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group: MUSCULOTROPIC ANTISPASMODIC/ANTIFLATULENT**

**ATC code: A03AX08 – Other drugs for functional gastrointestinal disorders.**

Alverine citrate is a musculotropic antispasmodic.

Simeticone is a physiologically inert substance which has thus no pharmacological activity. It acts by altering the surface tension of gas bubbles, leading to their coalescence.

### 5.2 Pharmacokinetic properties

After oral administration, simeticone is not absorbed and passes through the gastrointestinal tract before being excreted unchanged.

Alverine is absorbed from the gastrointestinal tract and rapidly converted into its pharmacologically active metabolite and into inactive metabolites. Peak plasma concentration is reached 1 hour - 1hour 30 minutes after oral administration. Renal excretion is the major route of elimination of the metabolites of alverine.

### 5.3 Preclinical safety data

Simeticone is chemically inert and is not absorbed systemically. Systemic toxic effects are therefore not expected.

Conventional non-clinical studies of repeated dose toxicity and genotoxicity, provide evidence that alverine citrate has no significant systemic toxicity.

Animal studies in two species do not indicate harmful effects with respect to embryotoxicity.

Peri- and post-natal study in the rat induced no harmful effects on the foetus development, on the delivery and on the growth and development of offspring during lactation period.

No studies to evaluate carcinogenicity, fertility and early embryonic development have been performed in animals.

## 6) PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Soft capsule shell:*

Gelatin, glycerol, titanium dioxide (E171).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

*PVC/Aluminium blister packs*

Store below 30°C.

*PVC/PE/PVDC-Aluminium blister packs*

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

20, 30 or 40 soft capsules in blister packs (PVC/PE/PVDC-Aluminium).
20, 30 or 40 soft capsules in blister packs (PVC/Aluminium).
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7) MARKETING AUTHORISATION HOLDER

Laboratoires MAYOLY SPINDLER
6 Avenue de l'Europe – B.P. 51
78401 CHATOU CEDEX – France
Standard: Tel.: +33 (0) 1 34 80 55 55
Medical information: Tel.: +33 (0) 1 34 80 72 60

## 8) MARKETING AUTORISATION NUMBERS

34009 278 526 4 0: 20 soft capsules in blister packs (PVC/PE/PVDC-Aluminium)
34009 278 527 0 1: 30 soft capsules in blister packs (PVC/PE/PVDC-Aluminium)
34009 278 528 7 9: 40 soft capsules in blister packs (PVC/PE/PVDC-Aluminium)
34009 332 540 6 3: 20 soft capsules in blister packs PVC/Aluminium
34009 343 259 1 5: 30 soft capsules in blister packs PVC/Aluminium
34009 333 799 3 3: 40 soft capsules in blister packs PVC/Aluminium.

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

Date of first authorisation: 05 June 1990
Date of latest renewal: 05 June 2010

## 10) DATE OF REVISION OF THE TEXT

10 March 2017.

## 11) DOSIMETRY

Not applicable.

## 12) INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

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## GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.