

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Spasmalvex 60 mg/300 mg, soft capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 60 mg alverine citrate and 300 mg simeticone.

Excipient with known effect: soya lecithin (traces).

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, soft.

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

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Relief of abdominal pain in irritable bowel syndrome.

Spasmalvex, soft capsule is indicated in adults only.

### 4.2 Posology and method of administration

#### Posology

#### *Paediatric population*

The safety and efficacy of Spasmalvex, soft capsules in children under 18 years of age have not been established.

#### Method of administration

For oral administration

#### *Adults (including the elderly)*

1 soft capsule two to three times daily at the beginning of meals.

### 4.3 Contraindications

Paralytic ileus

Intestinal obstruction

Use in pregnancy and lactation

History of allergic reaction or intolerance to alverine or to any of the excipients

Hypersensitivity to peanut or soya.

### 4.4 Special warnings and precautions for use

Other causes of gastro intestinal pathology should be outruled, and patients not improving after 2 weeks of treatment should be reviewed by physician.

#### **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/or in the case of jaundice, treatment with alverine/simeticone should be discontinued. Patients should be warned to report immediately any signs and symptoms of unexplained persistent nausea, decreased appetite, fatigue, vomiting, right upper abdominal pain, or jaundice, dark urine or pale faeces. Patients with these symptoms should discontinue taking Spasmalvex and the patient's hepatic function should be immediately evaluated.

#### **4.5 Interaction with other medicinal products and other forms of interactions**

None known.

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

##### Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

A moderate amount of data on pregnant women indicate no malformative or feto/ neonatal toxicity of alverine citrate. There are no data from the use of simeticone or the combination in pregnant women.

As a precautionary measure, it is preferable to avoid the use of Spasmalvex, soft capsules during pregnancy.

##### Breastfeeding

It is unknown whether alverine citrate or simeticone and their metabolites are excreted in human milk. This medicinal product should be avoided during breastfeeding.

##### Fertility

There are no data on the effects of alverine citrate or simeticone on human fertility.

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

Alverine/simeticone 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 side effects listed below have been reported at frequencies corresponding to: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ) and not known frequency (cannot be estimated on the basis of the available data).

Due to the presence of alverine:

##### **Hepatobiliary disorders**

*Very rare*

Cytolytic hepatitis (see section 4.4).

##### **Investigation**

*Not known*

Elevated transaminases, alkaline phosphatase, and bilirubin.

##### **Skin and subcutaneous tissue disorders**

*Not known*

Angioedema, skin rash, urticaria, and pruritus.

##### **Immune system disorders**

*Very rare*

Anaphylactic type reactions, and anaphylactic shock.

**Ear and labyrinth disorders**

*Not known*

Vertigo.

**Nervous system disorders**

*Not known*

Headache.

**Gastrointestinal disorders**

*Not known*

Nausea.

**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 the national reporting system:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

**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 / Anti-flatulent, ATC code: A03AX58

Alverine citrate is a non-atropinic, papaverine-like musculotropic antispasmodic.

Simeticone is an inert substance which has a physical action by altering the surface tension of gas bubbles, leading to their coalescence.

**5.2 Pharmacokinetic properties**

Simeticone is not absorbed from the gastrointestinal tract. Following oral administration, it is eliminated in unchanged form in the faeces.

A clinical study confirmed that alverine crosses the gastro-intestinal barrier with inter-individual variability. However in most patients, plasma concentrations were lower than 1ng/ml.

Steady-state for plasma concentrations of alverine were reached within 5 days, therefore no more increase in plasma levels is expected in case of repeated administration for a period of time longer than 7 days.

**5.3 Preclinical safety data**

Non clinical studies of single and repeated dose toxicity, genotoxicity, toxicity to reproduction and development provide evidence that alverine citrate has no significant systemic toxicity potential.

Simeticone is not absorbed from the intestinal lumen. Systemic effects are therefore not expected.

No long term studies to evaluate carcinogenicity have been performed in animals with alverine citrate or with the combination of alverine citrate and simeticone. Simeticone was shown to have no carcinogenicity potential.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Soft capsule shell:

Gelatin

Glycerol

Titanium dioxide (E171).

#### External lubricant composition:

Soya lecithin

Fractionated coconut oil.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

30 months

### 6.4 Special precautions for storage

Store below 25°C.

Keep in outer carton in order to protect from light.

### 6.5 Nature and contents of container

PVC/Aluminium thermoformed blister of 10 soft capsules.

Pack size of 20, 30, 60 or 90 capsules.

### 6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Laboratoires Galéniques Vernin

20, rue Louis-Charles Vernin

Dammarie-les-Lys

77190

France

## 8 MARKETING AUTHORISATION NUMBER

PA1927/002/001

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

Date of first authorisation: 12<sup>th</sup> March 2021

## 10 DATE OF REVISION OF THE TEXT