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.

4.4 Special warnings and precautions for use

Not available.

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 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

Not applicable.

4.8 Undesirable effects

The below adverse reactions 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).

Due to the presence of alverine citrate:

Hepatobiliary disorders
Very rare: case of liver disorder which resolves after treatment discontinuation.

Respiratory, thoracic and mediastinal disorders
Very rare: laryngeal oedema.

Skin and subcutaneous tissue disorders
Very rare: urticaria.

Vascular disorders
Very rare: shock.

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

Not available.

5) PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

MUSCULOTROPIC ANTISPASMODIC/ANTIFLATULENT

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 temperature 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 AUTHORIZATION HOLDER

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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 authorization: 05 June 1990
Last renewal: 05 June 2010

10) DATE OF REVISION OF TEXT

March 2015.

11) DOSIMETRY

Not applicable.

12) INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Not subject to medical prescription.