Marketing :	**Packaging :**

Regulatory :

Head Pharmacist / Global Manager :

MAYOLY

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Noir

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MeteoSpasmyl®

CAPSULES

Product Description:
Opaque white to yellowish oblong soft capsules, containing a thick whitish suspension.

Active ingredients:
Alverine citrate.....60 mg
Simeticone.....300 mg

Other ingredients:
Gelatine, glycerol, titanium dioxide (E171), for one capsule, oblong, colored white.

Box of 20 and 30 capsules
(blister pack of 10's)

Mechanisms of action:
A combination of a musculotropic spasmolytic, alverine citrate and a liquid silicone enriched with fine silica particles, simeticone gives MeteoSpasmyl® capsules its properties. Alverine citrate inhibits the action of smooth muscle contracturants agents. Simeticone acts as a protective film and as an antiflatulent and anti-distension agent. It also decreases gaseous distension by means of its antiwetting effect and its antifoaming effect, reinforced by the presence of silica.

Pharmacology:
The spasmolytic properties of alverine have been demonstrated in various experimental models such as fragments of isolated intestines of local intestinal motor activity, isolated gall bladder and uterus, bronchospasm and blood pressure. The results obtained in the various studies mentioned demonstrated that alverine is a substance with a spasmolytic action capable of inhibiting spasm of the smooth muscle fibres induced by different contracturant agents such as acetylcholine, histamine, serotonin or barium chloride.
Dimeticone and/or simeticone are used as antiflatulents in clinical practice because they decrease the surface tension of bubbles present in the stomach, enabling them to burst or form large air bubbles which can be easily expelled from the gastrointestinal tract.

Pharmacokinetics:
Both alverine citrate and simeticone are not significantly absorbed after oral administration, the clinical effects are resulting from the direct local pharmacological effect.

Indications:
This medication is an antispasmodic that reduces intestinal gas. This medication is recommended for relieving painful digestion with stomach distension. It is indicated for use in the relief of smooth muscle spasm, in conditions such as irritable bowel syndrome.

Warning for pregnancy and lactation:
Contraindicated in pregnancy and breast feeding

Effect on ability to drive and use machine:
METEOSPASMYL® has a minor influence on the ability to drive and use machines. Adverse effects such as vertigo have been reported in some patients. These types of disorders may affect the ability to drive and use machines.

Method of administration:
Oral route only.

Dosage:
For Adult use only: 1 capsule 2 to 3 times a day at the beginning of meals.

Contraindications:
Paralytic ileus (bowel obstruction due to lack of intestinal activity).
History of allergy reaction to or intolerance of alverine or one of the excipients.
Combination with sterculia (bulk-forming laxative) is contraindicated if patient has difficulty in swallowing.
Contraindicated in pregnancy and breastfeeding.

Side effects:
The adverse reactions listed below have been reported at frequencies corresponding to: very common; common; uncommon; rare; very rare and undetermined frequency (cannot be estimated on the basis of the available data).

Hepatobiliary disorders
Very rare: cytolytic hepatitis.

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.

Warnings and Precautions
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. 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.

Keep all medicine out of reach of children.
In case of doubt, do not hesitate to seek advice from your doctor or your pharmacist.

Drug interactions:
There are no known drug interactions reported with other drugs.
In order to avoid any potential interactions between several medications, you must systematically inform your doctor or pharmacist of all other current treatments.

Overdosage and management:
Cases of vertigo have been reported when a higher than recommended dosage is taken.

Storage:
Keep at dry and cool place not exceeding 30 °C.
Never use after the expiry date clearly indicated on the outer packaging.

Registered medicine n° MAL19990251ACZ

Manufacturer:
LABORATOIRES GALENIQUES VERNIN
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77190 DAMMARIE LES LYS France

Product Registration Holder:
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