Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alverine Mayoly Spindler 60mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 60 mg of alverine citrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules.

The hard gelatine capsules are white and oblong (size 3).

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The relief of smooth muscle spasm, in conditions such as irritable bowel syndrome, painful diverticular disease of the colon and primary dysmenorrhoea.

4.2 Posology and method of administration

Recommended dose and dosage schedules:

Adults (including the elderly): 1 or 2 capsules one to three times daily.

Children below the age of 12 years: not recommended.

4.3 Contraindications

- Paralytic ileus
- Known hypersensitivity to any of the ingredients
- Intestinal obstruction.

4.4 Special warnings and precautions for use

Additional warnings to be included in the Patient Information Leaflet:

If this is the first time you have had these symptoms, consult your doctor before using any treatment.

If any of the following apply do not use this medicinal product; it may not be the right treatment for you. See your doctor as soon as possible if:
- you are aged 40 years or over
- you have passed blood from the bowel
- you are feeling sick or vomiting
- you have lost your appetite or lost weight
- you are looking pale and feeling tired
- you are suffering from severe constipation
- you have a fever
- you have recently travelled abroad
- you are or may be pregnant
- you have abnormal vaginal bleeding or discharge
- you have difficulty or pain passing urine.

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks treatment.

4.5 Interaction with other medicinal products and other forms of interactions

Not stated.

4.6 Fertility, pregnancy and lactation

Although no teratogenic effects have been reported, use during pregnancy or lactation is not recommended as evidence of safety in preclinical studies is limited.

4.7 Effects on ability to drive and use machines

May cause dizziness. Do not drive or use machinery if affected.

4.8 Undesirable effects

Immune system disorders: Allergic reaction, anaphylaxis, dyspnoea and/or wheezing
Nervous system disorders: Headache, dizziness
Gastrointestinal disorders: Nausea
Hepato-biliary disorders: Jaundice due to hepatitis, typically this resolves on cessation of alverine
Skin and subcutaneous tissue disorders: Itching, rash

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:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

Can produce hypotension and atropine-like toxic effects. Management is as for atropine poisoning with supportive therapy for hypotension.

Fatality has occurred following overdose with very high doses.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for functional bowel disorders, ATC code: A03AX08

Alverine citrate is a spasmolytic, which has a specific action on the smooth muscle of the alimentary tract and uterus, without affecting the heart, blood vessels and tracheal muscle at therapeutic doses.

5.2 Pharmacokinetic properties

After oral administration, alverine is rapidly converted to its primary active metabolite, which is then further converted to two secondary metabolites. There is a high renal clearance of all metabolites indicating that they are eliminated by active renal secretion. The peak plasma level of the most active metabolite occurs between 1 and 1½ hours after oral dosing.

The plasma half-life averages 0.8 hours for alverine and 5.7 hours for the active primary metabolite.

5.3 Preclinical safety data

Although preclinical data are limited, those available indicate that alverine citrate has no significant potential for toxicity at the proposed dose level

Alverine citrate acts selectively on gut and uterine muscle, only affecting the heart, blood vessels and tracheal muscle at considerably higher doses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch (maize) pregelatinised
Magnesium stearate (E572)

Capsule shell
Gelatin
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Blister packs consisting of PVC/Aluminium.

Pack sizes of 3, 10, 12, 20, 30, 60, 90 or 100 white hard capsules.

Not all pack sizes may be marketed.

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 Mayoly Spindler
6 avenue de l'europe BP 51
78401 CHATOU Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA1993/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th June 2014
Date of last renewal: 28th April 2019

10 DATE OF REVISION OF THE TEXT

February 2019