Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spasmonal 60mg hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 60mg of alverine citrate.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Hard capsules.

An opaque size 3 capsule with a grey cap and blue body marked 'SP60'.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Spasmonal is indicated for use in the relief of smooth muscle spasm, in conditions such as irritable bowel syndrome and painful diverticular disease of the colon.

4.2 Posology and method of administration

Recommended dose and dosage schedules:

Adults: 1 or 2 capsules one to three times daily
Elderly: As adult dose
Children: Below the age of 12 not recommended
Method of administration
For oral use

4.3 Contraindications

- Paralytic ileus
- Intestinal obstruction
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

If any of the following apply do not use SPASMONAL 60mg; 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 of treatment.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Due to insufficient data use during pregnancy or lactation is not recommended.

4.7 Effects on ability to drive and use machines

Spasmonal may cause dizziness. Do not drive and/or use machines if affected.

4.8 Undesirable effects

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: 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); Not known (cannot be estimated from the available data)
The following undesirable effects were observed:

Immune system disorders
not known anaphylaxis, allergic reaction

Nervous system disorders
not known dizziness, headache

Respiratory, thoracic and mediastinal disorders
not known dyspnoea and/or wheezing

Gastrointestinal disorders
not known nausea

Hepatobiliary disorders
not known jaundice due to hepatitis (typically resolves on cessation of alverine), liver function test abnormal

Skin and subcutaneous tissue disorders
not known rash, itching

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 disorder,
ATC code: A03 AX08

Alverine citrate is a spasmolytic effective on smooth muscle of the alimentary tract. It is non-specific in that it is equally effective in reducing muscular contractions induced by acetylcholine, histamine or 5-hydroxytryptamine. It acts selectively on gut and uterine muscle, only affecting the heart, blood vessels and tracheal muscle at considerable higher 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

Preclinical studies provide evidence that alverine citrate has no significant systemic toxicity potential at the proposed dosage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Magnesium Stearate

Capsule shell

Gelatin
Indigo Carmine (E132)
Titanium Dioxide (E171)
Black Iron Oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container, in order to protect from light.

6.5 Nature and contents of container

Cartons of Aluminium foil/UPVC/PVDC blister packs containing 3 or 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

Mylan IRE Healthcare Limited
Unit 35/36
Grange Parade
Baldoyle Industrial Estate
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2010/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th October 1993

Date of last renewal: 18th October 2008

10 DATE OF REVISION OF THE TEXT

August 2018