Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alverine citrate 60mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 60mg alverine citrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (Capsule).

A Grey/Blue, size '3' hard gelatin capsules printed with ‘AV’ on cap and ‘60’ on body, containing white to off white powder.

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 or known hypersensitivity to any of the ingredients.
Intestinal obstruction
Use during pregnancy and lactation.

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 Alverine Citrate Capsules; 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 interaction

None 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. Use is therefore contraindicated during pregnancy and lactation.

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 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

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.

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

Pregelatinised Starch (Starch 1500)

Magnesium Stearate

Capsule shell Cap

Gelatin

Black Iron Oxide

Titanium Dioxide

Capsule Shell Body

Gelatin

Brilliant Blue

Titanium Dioxide

Printing Ink Composition

Shellac

Dehydrated Alcohol

Isopropyl Alcohol

Butyl Alcohol

Propylene Glycol

Strong Ammonia Solution

Black Iron Oxide (E172)

Potassium Hydroxide

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 packaging.

6.5 Nature and contents of container

Tablets are packed in Al//PVC/PVdC blisters containing 3, 10, 12, 20, 90 or 100 capsules, in strips of 10 capsules as appropriate. Not all pack size will be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Auden Mckenzie (Pharma Division) Ltd
Whiddon Valley
Barnstaple
North Devon
EX32 8NS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1352/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th December 2009

Date of last renewal: 30th October 2013

10 DATE OF REVISION OF THE TEXT

May 2018