SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Alverine Citrate 120 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 120mg alverine citrate
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (Caspule).
A Grey/Blue, size '1' hard gelatin capsules printed with ‘AV’ on cap and ‘120’ 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

Posology:

Adults (including the elderly)
1 capsule one to three times daily.

Children below the age of 12 years
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

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.

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

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:

<u>Immune system disorders</u>

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 this 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Symptoms

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 gastrointestinal disorders, ATC code: A03AX08.
Alverine citrate is an antispasmodic with a direct action on smooth muscle.

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

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 2, 10, 20, 30, 60 or 90 capsules, in strips of 10 capsules as appropriate.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
Ridings Point
Whistler Drive
Castleford
WF10 5HX
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2254

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/09/2009

10 DATE OF REVISION OF THE TEXT

29/09/2023