SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Alverine citrate 60 mg capsules

Stomach Pain & Cramps Relief 60 mg 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.

Size 3 hard Gelatin capsules, opaque grey cap and opaque blue body with "L" printed on cap and "60" printed on body filled with white to off white colour granular powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Alverine Citrate 60mg capsules is indicated for 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 and the elderly:

1 or 2 capsules 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 60 mg 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

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.

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

Fertility
There are no data on the effects of Alverine citrate on human fertility.

4.7 Effects on ability to drive and use machines

Alverine citrate 60 mg capsules may cause dizziness. Patients should not drive or use machines if they are 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 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:

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: A03 AX08 Antispasmodic

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,

Pregelatinized Maize starch

Magnesium Stearate

Capsule shell:

- Indigo carmine (E 132),
- Titanium dioxide (E 171),
- Gelatin.
- Iron oxide black (E 172),

Printing ink:

- Shellac (E 904),
- Propylene glycol (E 1520),
- Black iron oxide (E 172),
- Potassium hydroxide (E 525).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVDC-Alu blister containing packs of 2, 10, 12, 20, 90 or 100 capsules

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Noumed Life Sciences Limited

Noumed House, Shoppenhangers Road,

Maidenhead, Berkshire, SL6 2RB, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 44041/0119

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/10/2022

10 DATE OF REVISION OF THE TEXT

06/01/2025