

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Alverine Citrate 120mg Hard 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

Hard capsules

Hard gelatin capsules, size 1 with opaque blue colour body and opaque grey colour cap marked 'I 65' 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 and the elderly

1 or 2 capsules of 60mg or 1 capsule of 120mg, 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 Hard 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 ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Uncommon ($\geq 1/1,000$ to $< 1/100$); Rare ($\geq 1/10,000$ 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.

Treatment:

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.

Mechanism of action

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,
Starch, pregelatinised,
Magnesium stearate.

Capsule shell components:

Body

- Indigo carmine (E 132),
- Titanium dioxide (E 171),
- Gelatin.

Cap

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

Printing ink components:

- 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

36 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

PVC/PVdC-Alu blister containing packs of 7, 10, 14, 28, 30, 56, 60, 84, 90, 100 and 112 capsules are available.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Morningside Healthcare Ltd

Unit C, Harcourt Way

Leicester, LE19 1WP, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0290

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/06/2017

10 DATE OF REVISION OF THE TEXT

21/02/2023