Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alverine citrate 120mg capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains alverine citrate equivalent to 120mg alverine citrate.

Excipients with known effect:
Carmoisine (E122): 0.0420 mg/Capsule.
Tartrazine (E102): 0.0180 mg/Capsule.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsules.

Gelatin capsule shell size #1, with blue cap (marked as ALV) and white body (marked as 120), filled with white to off-white granular powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Alverine citrate 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

Method of administration
For oral administration.
Capsules should be swallowed whole.

Posology
Recommended dose and dosage schedules:

Adults (including the elderly):1 capsule one to three times daily.
Children below the age of 12 years: not recommended.

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 120 mg; it may not be the right treatment for you. See your doctor as soon as possible if you:
- are aged 40 years or over
- have passed blood from the bowel
- are feeling sick or vomiting
- have lost your appetite or lost weight

- are looking pale and feeling tired
- are suffering from severe constipation
- have a fever
- have recently travelled abroad
- are or may be pregnant
- have abnormal vaginal bleeding or discharge
- 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 interactions

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.
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

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:

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

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

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,
Magnesium stearate

Capsule Shell:
Gelatin,
Capsule Cap and body:
Brilliant blue (E133),
Carmoisine (E122),
Tartrazine (E102),
Titanium dioxide (E171)

Printing ink:
Shellac
Propylene Glycol
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, keep in the original packaging

6.5 Nature and contents of container

Aluminium foil, PVC/PVDC blister strip
Packs containing 20, 30, 60, 100 or 120 capsules

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

Incepta Euro Limited
29 Earlsfort Terrace
Dublin 2
DO2 AY28
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22965/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 11th March 2016

10 DATE OF REVISION OF THE TEXT

March 2020