

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Alverine citrate 60mg capsules, hard

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains alverine citrate equivalent to 60mg alverine citrate.

Excipients with known effect:

Carmoisine (E122): 0.0090 mg/Capsule.

Tartrazine (E102): 0.0360 mg/Capsule.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Hard capsules.

Gelatin capsule shell size #3, with blue cap (marked as ALV) and blue body (marked as 60), 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 or 2 capsules 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 60 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**

##### 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 ( $\geq 1/10$ ); 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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**

PA22965/001/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of First Authorisation: 11<sup>th</sup> March 2016

## **10 DATE OF REVISION OF THE TEXT**

March 2020