

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Alverine Citrate 60 mg Capsules

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains 60mg alverine citrate  
For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Capsule, hard (Capsule).  
A Grey/Blue, size '3' hard gelatin capsules printed with 'AV' on cap and '60' 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 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 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 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](http://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 3, 10, 12, 20, 90 or 100 capsules, in strips of 10 capsules as appropriate.

Not all pack size 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 00289/2253

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

30/09/2009

**10 DATE OF REVISION OF THE TEXT**

29/09/2023