1 NAME OF THE MEDICINAL PRODUCT
Alverine Citrate 60 mg Hard Capsules

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 dysmenorrhoa.

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.
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 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**
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 of adverse reactions after authorization 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 national reporting systems listed below:

**The United Kingdom**
MHRA

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 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
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
Blackrock Pharmaceuticals Ltd.
Abbey Place
24-28 Easton Street
High Wycombe, HP11 1NT
United Kingdom
8  MARKETING AUTHORISATION NUMBER(S)
   PL 33271/0002

9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE
    AUTHORISATION
   19/02/2016

10 DATE OF REVISION OF THE TEXT
   19/02/2016