Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spasmonal 60 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Spasmonal contains the following active ingredient:

Alverine Citrate 60mg per capsule.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard Capsules
Product imported from the UK:
Hard gelatin size 3 capsules for oral administration. Each blue/grey opaque capsule is marked 'SP60' on one half with a logo on the other half.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Spasmonal is indicated for use in the relief of smooth muscle spasm, in conditions such as irritable bowel syndrome and painful diverticular disease of the colon.

4.2 Posology and method of administration

Recommended dose and dosage schedules:

Adults: 1 or 2 capsules one to three times daily

Elderly: As adult dose

Children: Below the age of 12 not recommended

4.3 Contraindications

Cases of Paralytic ileus or known hypersensitivity to any of the ingredients.

Use during pregnancy and lactation.

4.4 Special warnings and precautions for use

Additional warnings to be included on 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 SPASMONAL 60mg; 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 of treatment.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Use contra-indicated during pregnancy and lactation

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Possible side effects may include nausea, headache, dizziness, itching, rash, and allergic reaction, including anaphylaxis.

There have been isolated cases of jaundice due to hepatitis, which may have been immune-mediated; but this adverse reaction resolved on cessation of alverine treatment.

4.9 Overdose

Can produce hypotension and atropine-like toxic effects. Management is as for atropine poisoning with supportive therapy for hypotension

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Alverine citrate is a spasmolytic effective on smooth muscle of the alimentary tract. It is non-specific in that it is equally effective in reducing muscular contractions induced by acetylcholine, histamine or 5-hydroxytryptamine. It acts selectively on gut and uterine muscle, only affecting the heart, blood vessels and tracheal muscle at considerable higher 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.

5.3 Preclinical safety data

Preclinical studies provide evidence that alverine citrate has no significant systemic toxicity potential at the proposed dosage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Magnesium Stearate
Gelatin
Indigo Carmine (E132)
Titanium Dioxide (E171)
Iron Oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from light
Store in a dry place

6.5 Nature and contents of container

Blisters in an overlabelled carton containing 100 capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18 Oxleasow Road
East Moon Moat
Redditch
Worcestershire B98 0 RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/045/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th February 2011

10 DATE OF REVISION OF THE TEXT

February 2012