Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spasmonal Forte 120 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 120mg alverine citrate.

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Hard capsules

Product imported from the UK:
Hard gelatin size 1 capsule for oral administration. Each blue/grey opaque capsule is marked ‘SP120’

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Spasmonal Forte 120mg is indicated for the 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 (including the elderly): 1 capsule one to three times daily.

Children below the age of 12 years: 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 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 SPASMONAL FORTE 120mg; 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 you 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

Use contraindicated 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 reactions, 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 acetyl choline, histamine or 5-hydroxytryptamine. It acts selectively on gut and uterine muscle, only affecting the heart, blood vessels and tracheal muscle at considerably 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
Capsule Shell:
Gelatin,
Indigo Carmine – (E132)
Titanium Dioxide – (E171)
Black Iron oxide – (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container 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.

6.5 Nature and contents of container

Cartons of aluminium foil/UPVC or aluminium foil UPVC/PVdc blister strips containing 60 capsules, in strips of 10 capsules as appropriate.

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Limited
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA465/264/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011

10 DATE OF REVISION OF THE TEXT