

Summary of Product Characteristics

Product Summary

- 1. Name of the Medicinal Product**
Altacite Plus Suspension
Asda Indigestion Liquid
Sainsbury's Spearmint Indigestion Liquid
- 2. Qualitative and quantitative Composition**
Each 5ml contains 500mg of Hydrotalcite light and 125mg of Dimethicone (activated)
- 3. Pharmaceutical Form**
Suspension

Clinical Particulars

- 4.1 Therapeutic indications**
Altacite Plus Suspension is indicated for the symptomatic relief of the following conditions: -
Dyspepsia, flatulence and abdominal hyperacidity, gastritis, peptic ulceration, heartburn especially when associated with oesophagitis or hiatus hernia, or heartburn in pregnancy.
- 4.2 Posology and Method of administration**
Route of administration: Oral
Adults
10ml suspension between meals and at bedtime.
Elderly:
No specific recommendations in the elderly.
Children (8-12 years)
Half the adult dose.
- 4.3 Contraindications**
None known
- 4.4 Special Warnings and Special Precautions for Use**
None Known
- 4.5 Interactions with other Medicaments and other forms of interaction**
Altacite Plus may reduce intestinal absorption of tetracyclines
.

4.6 Pregnancy and Lactation

For Co-simalcite 125/500 no clinical data on exposed pregnancies are available

Caution should be exercised when prescribing to pregnant women

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable Effects

Side effects are uncommon. Diarrhoea and vomiting have been reported but have ceased on withdrawal of the therapy.

4.9 Overdose

Overdose has not been reported. There is no evidence of absorption of Hydrotalcite in man. Investigations in healthy human volunteers have shown no elevation of serum aluminium or magnesium levels on administration of Hydrotalcite at therapeutic dosage for a continuous period of 28 days.

Pharmacological Properties

5.1 Pharmacodynamic Properties

Dimethicone is inert oil, which is tissue adherent and water repellent, it is therefore a mucosal protective and anti-foaming agent, which can reduce flatulence.

5.2 Pharmacokinetic Properties

No data on pharmacokinetic studies of Altacite Plus Suspension are available. The active ingredients hydrotalcite and activated dimethicone are not generally absorbed.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to that already included in the other sections of the SmPC.

Pharmaceutical Particulars

6.1 List of Excipients

Sodium carboxymethylcellulose, tween 80, sorbitan mono-oleate, sorbitan tristearate, glyceryl monostearate,

aerosil, methylcellulose 2500, microcrystalline cellulose, bronopol, spearmint polvaromas 077, saccharin sodium, chloroform and purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

60 Months. After first opening the container, discard the contents 28 days after opening.

6.4 Special precautions for storage

Store between 4⁰C and 25⁰C

6.5 Nature and Contents of container

High-density polyethylene bottles with standard jaypour caps or amber glass bottles with tamper evident polyethylene screw cap fitted with a polyethylene coated wool seal.

Bottle of 500ml as a pharmacy item or 100ml (and 250ml) as a general sales item.

6.6 Instructions for Use/Handling

Not applicable

Administrative Data

7.0 Marketing Authorisation Holder

Peckforton Pharmaceuticals Ltd.
Crewe Hall Crewe, Cheshire, CW1 6UL

8.0 Marketing Authorisation Number

PL 15760/0002

9.0 Date of first authorisation/renewal of the authorisation

3 June 1999

10.0 Date of (Partial) Revision of Text.

April 2004