

## SUMMARY OF PRODUCT CHARACTERISTICS

### Product Summary

**1. Trade Name of the Medicinal Product**

Hydrotalcite Suspension.

**2. Qualitative and Quantitative Composition**

Each 5ml contains 500mg of Hydrotalcite Light.

**3. Pharmaceutical Form**

Suspension

### Clinical Particulars

**4.1 Therapeutic indications**

Use as an antacid Hydrotalcite is indicated for symptomatic relief in the following conditions: peptic ulceration; dyspepsia; hyperacidity; gastritis, heartburn, especially when associated with reflux oesophagitis or hiatus hernia, and heartburn in pregnancy.

**4.2 Posology and Method of administration**

DOSAGE:

Adults

10ml between meals and at bedtime or as directed by the physician.

Elderly:

No specific recommendations.

Children (6-12 years)

Half the adult dose.

Children under 6 years:

Not recommended.

ADMINISTRATION:

Oral

**4.3 Contra-indications**

None known

**4.4 Special Warnings and Precautions for Use**

None stated

#### **4.5 Interaction with other Medications and other forms of Interaction**

Hydrotalcite suspension may interfere with the intestinal absorption of tetracyclines.

#### **4.6 Pregnancy and Lactation**

For Hydrotalcite 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**

None known.

#### **4.8 Undesirable Effects**

Side effects are uncommon. Diarrhoea and vomiting have been reported.

#### **4.9 Overdose**

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 administering of Hydrotalcite at therapeutic dosage for a continuous period of 28 days.

The sodium content of Hydrotalcite is 0.22mmol per 5ml.

### **Pharmacological Properties**

#### **5.1 Pharmacodynamic Properties**

Raising the pH of gastric contents to above 3.5 significantly reduces the pain and discomfort of acid associated symptoms, especially heartburn, dyspepsia, peptic ulceration, gastritis, and reflux oesophagitis. Hydrotalcite, buffering in the range of pH 3-5 over two hours, combines those properties of magnesium and aluminium based antacids in producing effective rises in pH over a considerable period.

#### **5.2 Pharmacokinetic Properties**

Not applicable

#### **5.3 Preclinical Safety Data**

Not applicable.

### **Pharmaceutical Particulars**

#### **6.1 List of Excipients**

Sorbitol USP, Carmellose Sodium BP, Veegum Regular, Sodium Propyl Hydroxybenzoate BP, Sodium Butyl Hydroxybenzoate BP, Hydrogen Peroxide 30% solution EP\*, Crème de Menthe 1951 and Purified Water.

\*Quantity includes an average of 70ppm.

#### **6.2 Incompatibilities**

None known

#### **6.3 Shelf life**

24 Months.

#### **6.4 Special precautions for storage**

Store between 25<sup>0</sup>C and 4<sup>0</sup>C . Do not freeze.

**6.5 Nature and Contents of Container**

Amber glass bottles and sealed by a white pigmented polypropylene tamper-evident closure.

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. Marketing Authorisation Holder**

Peckforton Pharmaceuticals Ltd.  
Crewe Hall  
Crewe  
Cheshire  
CW1 6UL

**8. Marketing Authorisation Numbers**

PL 15760/0003

**9. Date of first authorisation/renewal of the authorisation**

3 June 1999

**10. Date of (Partial) Revision of Text**

November 2002

**11. Legal Category**

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