SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Epsom Salts BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Sulfate Heptahydrate BP 100% W/W.

3. PHARMACEUTICAL FORM

Crystals or Crystalline Powder.

Brilliant colourless crystals or a white crystalline powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

1. For the relief of occasional constipation.
2. For the relief of pain from sprains, bruises and boils.

4.2 Posology and method of administration

1. Oral. As a dilute solution.
2. Cutaneous. As a concentrated solution or paste.

Recommended doses and dosage schedules

Indication 1

Adults and children over 12 years:	5-15g (1 – 3 teaspoons) to be taken as required in 250 ml of water, which may be flavoured with citrus juices.
The elderly:	To be used with caution, not exceeding the adult dose.

Indication 2

As a wet dressing suitable for all ages:	Dissolve one tablespoonful in a small cupful of warm water and apply with lint or cotton wool as required.

4.3 Contraindications

Internal use is contraindicated in all cases of acute gastro-intestinal conditions (except constipation), renal impairment, and in children with intestinal parasitic diseases.

Do not give internally to children under 12 years old.

Hypersensitivity to magnesium sulfate.

4.4 Special warnings and precautions for use

Keep out of the sight and reach of children.

Avoid prolonged use.

If symptoms persist for longer than 7 days consult your doctor.

Laxatives should not be taken where there is severe abdominal pain.

Osmotic laxatives may produce dehydration so sufficient water should always be taken.

Use with caution in elderly or debilitated patients.

4.5 Interaction with other medicinal products and other forms of interaction

Oral magnesium salts have the properties of antacids therefore it is recommended that this product is not taken within two to four hours of any other medicinal products to minimise interactions.

There is a risk of metabolic alkalosis when oral magnesium salts are given with polystyrene sulphonate resins. Magnesium salts, taken internally, potentiate the effects of competitive neuromuscular blocking drugs such as tubocurarine.
Magnesium salts may interfere with the absorption of many drugs including (but not limited to) ACE inhibitors (captopril, enalapril, fosinopril); antibacterials and antifungals (azithromycin, cefaclor, cefpodoxime, isoniazid,

itraconazole, ketoconazole, methenamine, tetracyclines, rifampicin and quinolone antibacterials); antivirals (atazanavir and tipranavir); antihistamines (fexofenadine); bisphosphonates; corticosteroids (deflazacort); dipyridamole; antiepileptics (gabapentin and phenytoin); ulcer healing drugs (lansoprazole); levothyroxine; mycophenolate; rosuvastatin; antipsychotics (sulpiride and phenothiazines); chloroquine and hydroxychloroquine; penicillamine, and digoxin if given concomitantly.

Alkaline urine may result, increasing excretion of aspirin. Magnesium salts possibly reduce absorption of bile acids and may reduce absorption of eltrombopag (give at least 4 hours apart). The plasma concentration of ulipristal may be reduced. Magnesium salts possibly reduce the plasma concentration of erlotinib (give at least 4 hours before or 2 hours after erlotinib).

4.6 Pregnancy and lactation

Do not use in pregnancy or while breastfeeding.

4.7. Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Hypermagnesaemia may occur after prolonged usage of magnesium sulfate as a purgative. May cause colic. Ingestion of magnesium salts may cause gastrointestinal irritation and watery diarrhoea. Rarely paralytic ileus has been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Though magnesium is poorly absorbed following oral administration there may be sufficient accumulation to produce toxic effects if given to a patient with impaired renal function.

Symptoms of hypermagnesaemia may include extreme thirst, a feeling of heat, hypotension due to vasodilation, drowsiness, nausea, vomiting, gastrointestinal irritation and watery diarrhoea, flushing, confusion, slurred speech, double vision and muscle weakness, loss of tendon reflexes due to neuromuscular blockade, CNS and respiratory depression, cardiac arrhythmias (including bradycardia), coma and cardiac arrest.

Treatment of mild hypermagnesaemia is usually limited to restricting magnesium intake. In severe hypermagnesaemia, ventilatory and circulatory support may be required. Slow intravenous injection of calcium gluconate (10 to 20ml of 10% calcium gluconate) is recommended to reverse the effects on cardiovascular and respiratory systems. If renal function is normal, adequate fluids should be given to promote renal magnesium clearance. This may be increased by the use of furosemide. Haemodialysis using a magnesium-free dialysis solution effectively removes magnesium, and this may be necessary in patients with renal impairment, or for whom other methods prove ineffective.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A06A D04 Osmotically acting laxatives

Magnesium sulfate is a saline purgative.

It can be employed locally in various inflammatory conditions, due to its osmotic action.

5.2. Pharmacokinetic properties

When a dilute solution of magnesium sulfate is taken by mouth, the absorption of water from the intestine is reduced, and the bulky fluid contents distend the bowel. Active peristalsis is excited and evacuation of the contents of the intestine results.

Magnesium salts cause the secretion of cholecystokinin from the duodenal mucosa, it has been suggested that cholecystokinin - mediated pancreatic secretion and increased secretion and motility of the small intestine and colon may contribute to the cathartic effect

Magnesium sulfate causes bowel evacuation normally within 2-4 hours.

5.3. Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

None.

6.2. Incompatibilities

Magnesium sulfate is incompatible with polymyxin B sulfate, with sodium and potassium tartrates, with soluble phosphates and arsenates and with alkali carbonates and bicarbonates in concentrated solution

6.3 Shelf life

36 months unopened

6.4. Special Precautions for Storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

300gm: Polypropylene securitainer with LDPE/HDPE white cap

6.6. Instructions for Use/Handling

None.

7 MARKETING AUTHORISATION HOLDER

L. C. M. Ltd.
Linthwaite Laboratories
Huddersfield
HD7 5QH

8. MARKETING AUTHORISATION NUMBER(S)

PL: 12965/0023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20.08.93

10 DATE OF REVISION OF THE TEXT

22/02/2016