Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Andrews Liver Salts Effervescent Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Effervescent powder containing magnesium sulphate (dihydrate) 17.4 % w/w, sodium hydrogen carbonate 22.6 % w/w and citric acid (anhydrous) 19.5 % w/w.

Excipient: Sucrose 40.5% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Effervescent powder.

A white free-flowing powder which effervesces on addition to water.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The product is recommended as a laxative and as an antacid for the treatment of dyspeptic symptoms.

4.2 Posology and method of administration

For oral use only.
Adults (including the elderly): As an antacid, one to two level spoonfuls (5-10 ml) in a glass of water. As a laxative, two level spoonfuls (10 ml) in a glass of water to be taken before breakfast or at bedtime.

Children (aged over 6 years): Half the adult dose.

Not suitable for children under 6 years of age except under medical advice.

4.3 Contraindications

This product should not be given to patients with a hypersensitivity to any component of Andrews Liver Salts or any previous hypersensitivity to Andrews Liver Salts.

This product should not be given to patients with symptoms of appendicitis, intestinal obstruction, inflammatory bowel disease, or abdominal pain of unknown origin.

4.4 Special warnings and precautions for use

Because of the sodium content, frequent use by patients on a low sodium diet should be avoided. This includes patients with hypertension and cardiac or renal dysfunction. Magnesium salts may cause central nervous depression in patients with renal dysfunction.

Because of the sucrose content, diabetics should use with caution. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase – isomaltase insufficiency should not take this medicine.
If a laxative is required every day, if there is persistent abdominal pain, or if symptoms persist consult your doctor. Prolonged continuous use is not recommended.

4.5 Interaction with other medicinal products and other forms of interaction

Magnesium sulphate, in common with other magnesium salts, may interfere with the absorption of tetracycline and alkalinisation of the urine may modify excretion of drugs for which the excretion is pH sensitive.

4.6 Fertility, pregnancy and lactation

For magnesium sulphate no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when recommending to pregnant (particularly during the first trimester) or lactating women.

4.7 Effects on ability to drive and use machines

No effect on mental alertness.

4.8 Undesirable effects

Diarrhoea may occur with extensive usage. Frequent or prolonged use in patients with severe renal dysfunction may lead to hypermagnesaemia and hypocalcaemia.

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 professional are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Diarrhoea may occur with excessive usage. Hypermagnesaemia and hypocalcaemia may also occur in the presence of impaired renal function. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium bicarbonate exerts an immediate antacid effect in the stomach by neutralising acid secretion with the liberation of carbon dioxide.

Citric acid and sodium bicarbonate in solution have a buffering capacity which alleviates discomfort caused by excess acidity in the stomach.

Magnesium sulphate is not readily absorbed from the intestine and acts as a saline purgative. Magnesium ions in the gut have also been shown to cause secretion of cholecystokinin which favours intraluminal accumulation of water and electrolytes.

5.2 Pharmacokinetic properties

The product has a local gastrointestinal action and so detailed pharmacokinetic data are not available. It has been shown that less than 10% of ionic magnesium is absorbed when the product was given to healthy subjects. The magnesium that is absorbed is excreted by the kidney.

After absorption, the bicarbonate is retained by the kidney to meet any deficit of bicarbonate in the plasma.

Citric acid is absorbed by the gastrointestinal tract and is oxidised in the body to carbon dioxide and water.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Tinplate tin: Five years.
Plastic container: Three years.

Use within 3 months of opening.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

Tinplate tin with tamper evident bleached kraft seal and pressfit lid containing 113 g or 227 g.

White oval plastic containers sealed with aluminium foil and fitted with a blue plastic overcap with hinged lid containing 150 g or 250 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited,
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8 MARKETING AUTHORISATION NUMBER

PA0678/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 February 1992

Date of last renewal: 25 February 2007

10 DATE OF REVISION OF THE TEXT

July 2025