SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Original Andrews Salts

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Effervescent Powder containing magnesium sulphate 17.4% w/w, Sodium Hydrogen Carbonate Ph Eur 22.6% w/w and Citric Acid (anhydrous) Ph Eur 19.5% w/w.

3 PHARMACEUTICAL FORM

Effervescent powder for oral use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The product is recommended as a laxative and as an antacid for the relief of upset stomach, indigestion and biliousness.

4.2 Posology and method of administration

Posology:

Original Andrews Salts is intended to be used by adults (including the elderly) and children aged 12 years and over.

Paediatric population:

Not suitable for children under 12 years of age.

Method of administration:

For oral administration.

As an antacid, measure one level spoonful (5 ml spoonful) and take in a glass of water repeated as necessary, up to a maximum of four times a day.

As a laxative, measure two level spoonfuls (two 5 ml spoonfuls) and take in

a glass of water before breakfast or at bedtime.

Children over 3 years: Half the adult

dose. Not suitable for children under

3 years of age.

Maximum duration of use is 14

days, unless advised by a physician.

4.3 Contraindications

Patients with impaired hepatic and renal function.

This product is contraindicated in patients with a prior hypersensitivity reaction to magnesium sulphate, sodium hydrogen carbonate, citric acid or any other ingredient of the preparation.

Persons on a sodium restricted diet e.g. those suffering from hypertension or congestive heart failure, should not use this product unless directed by a doctor.

4.4 Special warnings and precautions for use

Sodium content:
5 ml dosage contains 319 mg sodium.

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. Because of the sucrose content, diabetics should use with caution. If a laxative is required every day, if there is persistent abdominal pain, or if symptoms persist consult your doctor.

Do not exceed the recommended dose as excess of prolonged use may lead to alkalosis.

Treatment should be discontinued if there is no improvement in condition and medical advice should be sought. Persistent heartburn may be an early indicator of a more serious underlying condition.

Keep out of the sight and reach of children.

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.

The acid neutralizing capacity of the product may alter the absorption profile of pH specific drugs given concomitantly.

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 or lactating women.

4.7 Effects on ability to drive and use machines

Original Andrews Salts have no influence on the ability to drive and use machines.

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.

Minor gastrointestinal irritations, including belching, flatulence, and abdominal distention.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

Moderate, acute overdosage may result in belching and gastro-intestinal disturbances. Treatment would be withdrawal of the product and symptomatic measures, as appropriate.

Severe acute overdosage may precipitate sodium overload (hypernatraemia or hyperosmolality) and possibly metabolic alkalosis. Symptoms may include restlessness, weakness, thirst, reduced salivation, dizziness, headache and possibly hypotension and tachycardia. Treatment would consist mainly of appropriate correction of fluid-electrolyte balance.

Acute ingestion of the neat powder may lead to gastric irritation, gas liberation and possibly stomach perforation. Treatment would be general supportive and symptomatic measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

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

Citric acid and sodium hydrogen carbonate in solution have a buffering capacity which alleviates discomfort caused by 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 hydrogen carbonate is retained by the kidney to meet any deficit of hydrogen carbonate 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 are 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 Ph Eur.

6.2 Incompatibilities

None known.

6.3 Shelf life

Five years (tin and laminate sachets).
Three years (plastic containers).

6.4 Special precautions for storage

Store below 25°C and away from strong odours.

6.5 Nature and contents of container

Tin with tamper evident paper seal and pressfit lid containing 110 g, 113 g, 200 g or 227 g.

4 or 8 laminate sachets containing 5 g packed into cardboard cartons.

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

6.6 Special precautions for disposal and other handling

Use within 3 months of opening (plastic container only).

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights

Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0055

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 January 1990 / 28 November 1996

10 DATE OF REVISION OF THE TEXT

23/08/2023