

1. Trade name of the Medicinal Product

Asda Effervescent Health Salts
Boots Effervescent Health Salts
Morrisons Health Salts
Sainsbury's Healthcare Effervescent Health Salts
Superdrug Effervescent Health Salts
Wilko Effervescent Health Salts

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Effervescent powder containing Magnesium Sulphate 17.4% w/w, Sodium Bicarbonate Ph Eur 22.6% w/w and Citric Acid (anhydrous) Ph Eur 19.5% w/w.

3 PHARMACEUTICAL FORM

Effervescent Powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is recommended for symptomatic relief of upset stomach, heartburn, indigestion and biliousness and as a laxative.

4.2 Posology and method of administration

Dosage:

Adults

Upset stomach, heartburn, indigestion and biliousness; Take 1 or 2 teaspoonfuls in a glass of water.

As a laxative: Take two teaspoonfuls in a glass of water before breakfast or at bedtime.

Childrens dosage

Not suitable for children under 3 years old.

For children over 3 years old reduce the dose appropriately depending on size and age.

Method of administration: oral after addition to water.

4.3 Contraindications

Do not use in children under 3 years old.

Hypersensitivity to any of the ingredients. Do not use in patients with acute gastrointestinal conditions.

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 and renal dysfunction. Because of the sucrose content, diabetics should use with caution.

If a laxative is needed every day, or there is persistent abdominal pain, or if symptoms persist consult your doctor.

Not suitable for children under 3 years old. Keep out of the reach of children.

Caution should be taken in pregnancy and in the elderly and debilitated. Avoid prolonged use.

4.5. Interaction with other Medicaments and other forms of Interaction

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

4.6. Fertility, Pregnancy and Lactation

As with other medicines, caution should be exercised in pregnancy. Magnesium is known to cross the placenta. Patients should seek the doctor's advice if pregnant or breastfeeding.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

4.7 Effects on ability to drive and use machines

None stated.

4.8. Undesirable Effects

Colic, diarrhoea, belching; Frequent or prolonged use in patients with severe renal dysfunction may lead to alkalosis and 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 professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 is an antacid, citric acid increases the secretion of urine and renders it less acid and magnesium sulphate is a saline purgative.

5.2 Pharmacokinetic properties

The therapeutic action of this product occurs within the gastrointestinal tract. Bioavailability studies are irrelevant to a product of this nature.

5.3 Preclinical safety data

N/A.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose. The product contains 8.1mmol Sodium per 3g (level teaspoonful)

6.2 Incompatibilities

None stated.

Pharmaceutical Particulars

6.3. Shelf Life

18 months

6.4 Special precautions for storage

Store below 25°C in a dry place and away from strong odours. Once opened use within 3 months.

6.5 Nature and contents of container

Foil lined composite drum with foil membrane and polyethylene lever lid containing 113g or 227g.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited

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Braunton

North Devon

EX33 2DL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0039

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

20th August 2003

10 DATE OF REVISION OF THE TEXT

04/05/2016