ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

ENO ACTIVE FRUIT SALTS - MINT FLAVOUR (Powder)

ENO ACTIVE FRUIT SALTS (Powder)

ENO ACTIVE FRUIT SALTS - ORANGE FLAVOUR (Powder)

ENO ACTIVE FRUIT SALTS REGULAR (Powder)

COMPOSITION:

ENO ACTIVE FRUIT SALTS - MINT FLAVOUR (Powder)

ENO ACTIVE FRUIT SALTS (Powder)

Each 5,0 g dose contains:

Sodium Bicarbonate	2,32 g
Anhydrous Citric Acid	2,18 g
Sodium Carbonate	0,50 g

ENO ACTIVE FRUIT SALTS

ENO ACTIVE FRUIT SALTS - ORANGE FLAVOUR

Each 5,0 g dose contains:

Sodium Bicarbonate	2,29 g
Anhydrous Citric Acid	2,16 g
Sodium Carbonate	0,50 g

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

Inactive ingredients:

ENO ACTIVE FRUIT SALTS REGULAR FLAVOUR

The inactive ingredient is Purified Water 0,00375 g.

ENO ACTIVE FRUIT SALTS

The inactive ingredients include Purified Water 0,00371 g, Saccharin Sodium 0,002 g and Evercool cooling flavour 0.0508 g.

ENO ACTIVE FRUIT SALT - MINT FLAVOUR

The inactive ingredients includes Purified Water 0,00375 g, Sodium Saccharin 0,004g, Sodium Cyclamate 0,015g, Peppermint flavour 0.015 g, Cooling flavour Evercool 0.005 g and Colour Green Powder 0,0019g.

ENO ACTIVE FRUIT SALT – ORANGE

The inactive ingredients includes Purified Water 0,00375 g, Saccharin Sodium 0,008 g, Flavour Orange 0,05 g and Colour Sunset yellow 0,002 g.

PHARMACOLOGICAL CLASSIFICATION:

A 11.4 Antacids

PHARMACOLOGICAL ACTION:

ENO ACTIVE FRUIT SALTS has antacid activity and renders the urine less acidic.

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

INDICATIONS:

- As an antacid: e.g. for the fast relief of indigestion and heartburn.
- As a urinary alkaliniser

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients of ENO ACTIVE FRUIT SALTS, including excipients.

Avoid use if suffering from hypertension, heart failure or cirrhosis of the liver and in patients with impaired hepatic and renal failure.

ENO ACTIVE FRUIT SALTS should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

Should not be given with urinary antiseptics which require an acid urine, such as methenamine mandelate and methenamine hippurate.

WARNINGS AND SPECIAL PRECAUTIONS

Use with care in patients suffering from oedema and renal insufficiency.

ENO ACTIVE FRUIT SALTS does not eradicate bacteriuria, although they may temporarily relieve lower urinary tract symptoms.

Do not use in patients with congestive heart failure or hypertension except under the advice and supervision of a doctor.

Not to be used excessively. If there is persistent discomfort, a doctor should be consulted.

Citric acid ingested frequently or in large quantities may cause erosion of the teeth and local irritation.

Excessive doses may lead to sodium overloading and hyperosmolality.

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

Contains sodium. Persons on a sodium-restricted diet should not take multiple doses of ENO ACTIVE FRUIT SALTS unless directed by a doctor. Excessive administration may lead to metabolic alkalosis especially in patients with impaired renal function.

Effects on ability to drive and use machinery:

No significant effect on the ability to perform task that require judgement, motor, or cognitive skills.

INTERACTIONS:

ENO ACTIVE FRUIT SALTS may interact with many medicines, affecting the rate and/or extent of their absorption.

Sodium bicarbonate administration leads to alkalinisation of the urine resulting in increased renal clearance of acidic medicines, or decreased renal clearance of basic medicines which may result in toxicity.

Sodium bicarbonate enhances lithium excretion.

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

As an antacid:

ADULTS: One 5 ml medicine measure or one sachet in a glass of water.

A second dose may be taken after 2-3 hours.

Minimum dosing interval: 2 hours

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

Maximum daily dose (MDD): 2 x 5 ml medicine measures or 2 sachets.

Maximum duration of antacid use at MDD: 14 days.

As a urinary alkaliniser:

ADULTS: One 5 ml medicine measure or one sachet well diluted with water to be taken after meals morning and evening.

ENO ACTIVE FRUIT SALTS should not be used in children under 12 years.

SIDE EFFECTS:

Frequencies of the following side effects are unknown.

Gastrointestinal disorders: Flatulence, stomach cramps, abdominal distension.

Citric acid ingested frequently or in large quantities may cause erosion of the teeth and local irritation.

Not to be used excessively. If there is persistent discomfort, consult a doctor.

Metabolic disorders: Excessive administration may lead to metabolic alkalosis especially in patients with impaired renal function. Symptoms may include shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions and coma. Muscle hypertonicity, twitching and tetany may develop especially in hypocalcaemic patients. (See WARNINGS AND SPECIAL PRECAUTIONS)

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See SIDE EFFECTS

Excessive administration of sodium bicarbonate may lead to metabolic alkalosis.

Treatment is supportive and symptomatic and consists mainly of correction of fluid and electrolyte balance. A doctor should be consulted in known cases of overdosage.

IDENTIFICATION:

ENO ACTIVE FRUIT SALTS – MINT FLAVOUR: A light green, free flowing powder. Characteristic mint odour.

ENO ACTIVE FRUIT SALTS: A white, free-flowing powder.

ENO ACTIVE FRUIT SALTS - ORANGE FLAVOUR: Pale orange, free flowing powder.

ENO ACTIVE FRUIT SALTS REGULAR: White, free flowing powder.

PRESENTATION:

All flavours:

Bottles containing 100 g and 200 g.

Packs of 72 x 5 g sachets.

Travel packs of 10 x 5 g or 20 x 5 g sachets.

ENO ACTIVE FRUIT SALTS REGULAR only:

Packs of 82 x 5 g or 90 x 5 g sachets.

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

STORAGE INSTRUCTIONS:

Keep in a cool (below 25 °C), dry place.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS:

ENO ACTIVE FRUIT SALTS - MINT FLAVOUR:	Z/11.4/13
ENO ACTIVE FRUIT SALTS	Y/11.4/186
ENO ACTIVE FRUIT SALTS - ORANGE FLAVOUR:	Y/11.4/187
ENO ACTIVE FRUIT SALTS REGULAR:	Y/11.4/185

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE:

Haleon South Africa (Pty) Ltd

11 Hawkins Avenue

Epping Industria 1

Cape Town

7450

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date of registration of medicine:

14 JUNE 1991

ENO ACTIVE FRUIT SALTS MINT FLAVOUR only:

20 JANUARY 1992

ENO ACTIVE FRUIT SALT (All FLAVOURS)
Package Insert

Date of last CCC approved amendment:

17 December 2017