SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM

ENO TABLETS ORANGE FLAVOUR CHEW TABLET**.**

Read all of this leaflet carefully because it contains important information for you

ENO TABLETS ORANGE FLAVOUR CHEW TABLET is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ENO TABLETS ORANGE FLAVOUR CHEW TABLET carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ENO TABLETS ORANGE FLAVOUR CHEW TABLET with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

COMPOSITION

The active substances are 500 mg calcium carbonate, in each tablet.

The other ingredients are Sucrose Powdered, Starch (Maize Starch), Light Liquid Paraffin, Talc, Sodium Hexametaphosphate, Purified Water. Flavour Tetrarome Orange, Adipic acid. Contains sugar (sucrose)

APPROVED INDICATIONS AND USE

ENO TABLETS ORANGE FLAVOUR is recommended for the Relief from heartburn and acid indigestion.

INSTRUCTIONS BEFORE TAKING ENO TABLETS ORANGE FLAVOUR

Do not take ENO TABLETS ORANGE FLAVOUR

- if you are hypersensitive (allergic) to calcium carbonate, or any of the other ingredients of ENO TABLETS ORANGE FLAVOUR (see "COMPOSITION").
- If you have renal, liver or heart failure
- If you are pregnant or breastfeeding

Take special care with ENO TABLETS ORANGE FLAVOUR:

- if your symptoms do not improve within 10 days of continuous use. Please consult your doctor.
- ENO TABLETS ORANGE FLAVOUR should not be given to children under 12 years of age unless prescribed by a doctor.
- if you have a history of high blood pressure or heart disease.
- if you have a history of constipation
- if you have impaired (reduced) renal function.

Do not exceed the recommended dose.

Taking ENO TABLETS ORANGE FLAVOUR with food or drink:

ENO TABLETS ORANGE FLAVOUR should be taken after meals and at bedtime. Do not exceed 16 tablets in a 24-hour period.

Human Reproduction:

ENO TABLETS ORANGE FLAVOUR should not be taken during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby while taking ENO TABLETS ORANGE FLAVOUR, please consult your doctor, pharmacist or other healthcare professional for advice.

Effects on ability to drive and use machines:

None established to date.

Using other medicines with ENO TABLETS ORANGE FLAVOUR:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines. May interfere with the absorption of other medicines if given concomitantly.

INSTRUCTIONS ON HOW TO TAKE ENO TABLETS ORANGE FLAVOUR

Always take ENO TABLETS ORANGE FLAVOUR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Use the lowest effective dose for the shortest possible duration of treatment.

The usual dose is:

Adults and children ages 12 and over: Chew 1 or 2 tablets after meals and at bedtime.

Not to be given to children under the age of 12 except on medical advice.

Do not exceed 16 tablets in a 24-hour period.

If you take more ENO TABLETS ORANGE FLAVOUR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Hypercalcaemia and alkalosis which may occur with excessive doses responds to withdrawal of the tablets.

If you forget to take a dose of ENO TABLETS ORANGE FLAVOUR:

Do not take a double dose to make up for forgotten individual doses.

SIDE EFFECTS

ENO TABLETS ORANGE FLAVOUR can have side effects.

Not all side effects reported for ENO TABLETS ORANGE FLAVOUR are included in this leaflet. Should your general health worsen while receiving ENO TABLETS ORANGE FLAVOUR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking ENO TABLETS ORANGE FLAVOUR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you experience constipation
- Any abnormal high levels of calcium in the blood.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to *ENO TABLETS ORANGE FLAVOUR*. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- You experience unexplained high levels of calcium in the blood.

***The following side effects may occur, but the frequency is unknown*:**

CALCIUM CARBONATE:

- High levels of calcium in the blood
- Renal function disturbance

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSAL INFORMATRION OF ENO TABLETS ORANGE FLAVOUR:

Keep all medicines out of the reach and sight of children.

Store in a cool (at or below 25 °C) dry place.

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF ENO TABLETS ORANGE FLAVOUR:

Blister packs comprising of PVC/aluminium foil containing 12 or 24 tablets, packed into cardboard cartons.

IDENTIFICATION OF ENO TABLETS ORANGE FLAVOUR:

Orange slightly mottled tablet with bevelled edges. Embossed ENO on one side. Characteristic orange odour and refreshing slightly effervescent orange flavor.

REGISTRATION NUMBER

M/11.4/6

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Haleon South Africa (Pty) Ltd

11 Hawkins Avenue

Epping Industria 1

Cape Town

7450

Telephone number: 0800 007 018

DATE OF PUBLICATION

Date on the registration certificate of the medicine: **23 April 1980**

Date of most recently revised package insert as approved by the Council: **22 June 2018**