Summary of Product Characteristics for Pharmaceutical Products

1. NAME OF THE MEDICINAL PRODUCT

Visocn (Sodium Alginate 250mg, Sodium Bicarbonate 133.5mg & Calcium Carbonate 80mg) Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml solution contains:

Sodium Alginate BP.....250 mg

Sodium Bicarbonate BP...133.5 mg

Calcium Carbonate.....80 mg
Flavour: Peppermint

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension

White coloured, peppermint flavoured oral suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indication

This medicine alleviates the painful conditions resulting from the reflux of gastric acid and bile into the oesophagus by suppressing the reflux itself. It is indicated in heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia, reflux oesophagitis, regurgitation and all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

4.2. Posology and method of administration

Posology

Adults and children over 12 years

Two to four 5 ml spoonfuls.

Children 6-12 years

One to two 5 ml spoonfuls

children under six years of age

Not recommended in.

Method of administration

Oral administration

Doses should be taken after meals and at bedtime.

4.3. Contra-indications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4. Special warnings and special precautions for use

- If symptoms do not improve after seven days, the clinical situation should be reviewed.
- Each 10 ml dose of this medicine contains about 6 mmoles of sodium and therefore care should be exercised in patients on a sodium restricted diet.
- Each 10 ml dose contains 160 mg (1.6 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
- This medicine should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 2 weeks if symptoms persist.
- This medicine should not be used by patients allergic to any of its constituents.

4.5 Interaction with other medicinal products and other forms of interaction

A time-interval of 2 hours should be considered between this medicine intake and the administration of other medicinal products, especially *tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine and biphosphonates (diphosphonates) and estramustine*. See also 4.4. Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionisation of the other drug. Antacids reduce the absorption of certain drugs from the following groups: *ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.*

Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.

Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

4.6 Fertility ,Pregnancy and Lactation

Pregnancy

Clinical studies in more than 500 pregnant women as well as a large amount of data from postmarketing experience indicate no malformative nor feto /

neonatal toxicity of the active substances. This medicine can be used during pregnancy, if clinically needed.

Breast feeding:

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers.

This medicine can be used during breast-feeding.

Fertility:

Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction.
Clinical data do not suggest that this medicine has an effect on human fertility.

4.7. Effects on ability to drive and use machines

There are no effects on ability to drive or operate machinery.

4.8. Undesirable Effects

Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	**Frequency**	**Adverse Event**
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm.

4.9 Overdose

As this medicines mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal distension which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in this medicine would also make serious consequences from overdosage very unlikely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

On ingestion the product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents, quickly and effectively impeding gastrooesophageal reflux, for up to 4 hours. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

5.2 Pharmacokinetic Properties

Alginic acid is not absorbed into the systemic circulation.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sodium Methyl Paraben, Sodium Propyl Paraben, Sodium Benzoate, Bronopol, Sodium Saccharine Sorbitol Solution 70 %, Menthol, Propylene Glycol, Colloidal Silicon Dioxide, Flavour: Peppermint & Purified Water.

6.2. Incompatibilities

None

6.3. Shelf Life

36 months

6.4. Special Precautions for Storage

Store below 30^{o}C.
Do not refrigerate or freeze.

Keep out of reach of children

SHAKE WELL BEFORE USE

6.5. Nature and contents of container

150 ml PET Bottles

Pack size: 1 x 150 ml PET Bottles in one carton box along with packing leaflet.

6.6. Special precautions for disposal and other handling

None

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:

Eastleigh Pharmaceuticals Co. Ltd
P.O Box 167-00610
Nairobi, Kenya

Manufacturing site address:

MARS REMEDIES PVT LTD
Address: 635, GIDC Estate,
Waghodia-391760, Vadodara,
GUJARAT INDIA

8. Marketing authorization number

CTD9430

9. Date of first registration

11/11/2022

10. Date of revision of the text:

15/09/2023

11. DOSIMETRY (IF APPLICABLE)

Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals (If Applicable):

Not Applicable