SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sainsbury's Healthcare Orange Flavoured Antacid 500 mg Tablets
Boots Indigestion Relief Orange Flavour 500 mg Tablets
Tesco Health Heartburn & Indigestion Relief Orange Flavour 500mg Tablets
Wilko Orange Flavoured Antacid 500 mg Tablets
Asda Orange Flavoured Antacid 500mg Tablets
Superdrug Orange Flavoured Indigestion Relief 500 mg Tablets
Morrisons Orange Flavoured Antacid 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg calcium carbonate.

Excipients with known effect
Each tablet contains 521mg of dextrose monohydrate.
Each tablet contains 2.33mg of sunset yellow.
Each tablet contains approximately 0.88mg of lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1. Therapeutic indications

For relief from indigestion, dyspepsia, heartburn, acidity and flatulence.

4.2 Posology and method of administration

Take one or two tablets, as required, up to a maximum of 12 tablets a day.

Suck slowly or chew as preferred.

There is no distinction between adults and the elderly on the pack.

Not recommended for children under 12 years.

4.3 Contraindications

- Hypersensitivity to the active ingredients, excipients, refer to section 6.1
- Patients with hypercalcaemia, hyperparathyroidism, hypercalciuria, nephrolithiasis and Zollinger-Ellison syndrome.
- Patients on a low phosphate diet.
- Patients on cardiac glycosides.
- Patients with impaired renal function.
- Nephrocalcinosis
- Patients with renal calculi, or with a history of renal calculi
- Hypophosphatemia

4.4 Special warnings and precautions for use

If symptoms persist consult your doctor.
Keep all medicines out of the sight and reach of children.

Long term uses at high doses can result in undesirable effects such as hypercalcaemia and milk-alkali syndrome. Prolonged use possibly enhances the risk for the development of renal calculi.

The elderly should take care to observe warnings and contraindications, due to increased susceptibility to adverse drug reactions, by means of age-related changes and polypharmacy.

Prolonged use should be avoided. The stated dose should not be exceeded and if symptoms persist, despite 7 days of continuous therapy, the clinical situation should be reviewed by a medical professional. Diagnostic measures are recommended in order to rule out a more serious disease.

This medicinal product contains dextrose.
Patients with rare glucose-galactose malabsorption should not take this medicine.
Contains approximately up to 1g dextrose per dose. This should be taken into account in patients with diabetes mellitus.

This medicinal product contains lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicinal product contains sunset yellow.
May cause allergic reactions.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed. Due to the presence of calcium carbonate which act as an antacid, a time-interval of 2 hours should be considered between [PRODUCT] intake and the administration of other medicinal products.

In common with other antacids, calcium carbonate may form complexes with certain drugs e.g., antibiotics (such as tetracyclines and quinolones) and cardiac glycosides (digoxin), H2-antihistaminics, fluoroquinolone, iron containing drugs, ketoconazole, neuroleptics, thyroxine, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, and diphosphonates leading to their reduced absorption. This should be taken into account when concomitant administration is considered.

Thiazide diuretics reduce the urinary excretion of calcium and increase the serum calcium.

4.6. Fertility, pregnancy and lactation

Pregnancy:

Studies in animals have not been done.

Calcium containing drugs are used widely in pregnancy by way of oral calcium supplements or antacid therapy. No relationship between malformations in general and calcium exposure has been noted. Although a weak association with CNS malformations and exposure in the first 4 months of pregnancy has been detected in one large study

Caution should be exercised when prescribing to pregnant women.

Lactation:

There is no information relating to the excretion of this medicine in breast milk. Calcium carbonate can be used during lactation if taken as instructed. However, no problems would be anticipated from the use of this product during lactation, if taken in accordance with the posology.

4.7. Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Calcium Carbonate can cause constipation and flatulence.
Hypercalcaemia can occur as can alkalosis following the regular use of Calcium Carbonate. The milk-alkali syndrome has occasionally occurred in patients taking large doses. ‘Acid Rebound’ has been reported on cessation of Calcium Carbonate.

Immune System Disorders:
Hypersensitivity, anaphylactic reaction.

Metabolism and Nutrition Disorders: Hypercalcaemia, alkalosis.

Gastrointestinal Disorders:
Eructation, constipation, nausea, vomiting, abdominal discomfort, diarrhoea.

Musculoskeletal and Connective Tissue Disorders:

Muscular weakness.

Skin and Subcutaneous Disorders:
Rash, urticaria, angioedema.

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

Excessive ingestion of calcium carbonate, especially in patients with impaired renal function can lead to hypercalcaemia, renal insufficiency and alkalosis, characterised by gastro-intestinal symptoms (pain, nausea, vomiting, constipation) and muscular weakness. In these cases, the intake of the product should be stopped and adequate isotonic fluid intake encouraged. In severe cases of overdosage, milk-alkali syndrome may occur.

Treatment should be symptomatic and supportive. Haemodialysis and other therapeutic measures such as saline diuresis have been used to treat successfully the excessive ingestion of calcium carbonate antacid..

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antacid.

Mechanism of Action/Effect
Calcium Carbonate reacts chemically to neutralise or buffer existing quantities of stomach acid but has no direct effect on its output. This action results in increased pH value of stomach contents, thus providing relief of hyperacidity symptoms. It also reduces acid concentration within the lumen of the oesophagus, thus causing an increase in intra-oesophageal pH and a decrease in pepsin activity, which aids in the control of gastro-oesophageal reflux.

ATC code: A02AC01.

5.2. Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already stated in other sections of the SPC.

6.1. List of Excipients

Pregelatinised
Starch
Microcrystalline
Cellulose
Maize Starch
Dextrose
Monohydrate
Sodium Saccharin
Magnesium
Stearate
Sunset Yellow
Lake E110
Orange Flavour
(including lactose)

6.2. Incompatibilities

None known.

6.3. Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5. Nature and Contents of Container

250 micron clear PVC/20 micron hard temper, heat seal coated aluminium foil.
24, 48, 72, 96 tablets/carton.

6.6. Instructions for use, handling and disposal

None.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited

Wrafton
Braunton
North Devon
EX33 2DL

8. MARKETING AUTHORISATION NUMBER

PL 12063/0018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First Authorisation: 28th July 1993

10 DATE OF REVISION OF THE TEXT

05/08/2024