PACKAGE INSERT FOR CLICKS ALGINIC ANTACID SUSPENSION

SCHEDULING STATUS

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PROPRIETARY NAME (AND DOSAGE FORM):

CLICKS ALGINIC ANTACID SUSPENSION (Suspension)

COMPOSITION

Each 10 mL contains:	Sodium bicarbonate	267 mg
	Sodium alginate	500 mg
	Calcium carbonate	160 mg
Preservatives:	Methyl hydroxybenzoate	0,4 % *m/v*
	Propyl hydroxybenzoate	0,06 % *m/v*
Total sodium content:	6,052 mmol/10 mL	

Other inactive ingredients include carmellose sodium, peppermint flavour and saccharin sodium.

PHARMACOLOGICAL CLASSIFICATION

A 11.10 Drugs acting on gastrointestinal tract (special combinations).

PHARMACOLOGICAL ACTION

CLICKS ALGINIC ANTACID SUSPENSION has antacid properties and forms a viscous layer in the stomach.

INDICATIONS:

CLICKS ALGINIC ANTACID SUSPENSION is indicated for gastric reflux, mild to

moderate reflux oesophagitis, heartburn, heartburn of pregnancy (see **"PREGNANCY AND LACTATION"**) and hiatus hernia.

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients in CLICKS ALGINIC ANTACID SUSPENSION.
- CLICKS ALGINIC ANTACID SUSPENSION should not be administered to patients with metabolic or respiratory alkalosis, hypercalcaemia and hypochlorhydria.

WARNINGS AND SPECIAL PRECAUTIONS:

Do not use the maximum dosage of CLICKS ALGINIC ANTACID SUSPENSION for more than 2 weeks, except under the advice and supervision of a doctor.

Do not use CLICKS ALGINIC ANTACID SUSPENSION if you are on a sodium restricted diet, or suffering from hypertension or heart failure, except under the supervision of a doctor.

CLICKS ALGINIC ANTACID SUSPENSION should be administered with caution to patients with congestive cardiac failure, oedema, renal impairment, cirrhosis of the liver, hypertension and to patients receiving corticosteroids (see **INTERACTIONS"**).

CLICKS ALGINIC ANTACID SUSPENSION can cause stomach cramps and flatulence.

Hypercalcaemia and alkalosis can occur following high doses of calcium carbonate. With long-term or prolonged use, antacids containing sodium bicarbonate, such as

CLICKS ALGINIC ANTACID SUSPENSION, may cause hypercalcaemia associated with milk-alkali syndrome.

Overuse or prolonged use of calcium carbonate, as in CLICKS ALGINIC ANTACID SUSPENSION, may give rise to renal calculi.

Large doses of CLICKS ALGINIC ANTACID SUSPENSION may interfere with the absorption of some medicines (see **"INTERACTIONS"**).

Effects on the ability to drive and operate machinery

It is unlikely that CLICKS ALGINIC ANTACID SUSPENSION will impair the ability to drive or operate machinery.

INTERACTIONS

Due to the ability of the antacids in CLICKS ALGINIC ANTACID SUSPENSION to change gastric or urinary pH and to adsorb or form complexes with other medicines, the rate and/or extent of absorption of other medicines may be increased or reduced when such medicines are used concurrently (see **"SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS"**). In general, patients should be advised not to take any other oral medicines within 1 to 2 hours of CLICKS ALGINIC ANTACID SUSPENSION. Medicines of which the absorption may be decreased include, but are not limited to, anticholinergics, H_2-receptor antagonists, oral iron preparations, ketoconazole, tetracyclines, and phenytoin.

CLICKS ALGINIC ANTACID SUSPENSION should be administered with caution to patients receiving corticosteroids (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

Concurrent use of thiazide diuretics with large doses of calcium carbonate, as in CLICKS ALGINIC ANTACID SUSPENSION may result in hypercalcaemia.

Concurrent and prolonged use of milk and milk products with calcium carbonate or sodium bicarbonate, as in CLICKS ALGINIC ANTACID SUSPENSION may result in the milk-alkali syndrome.

Potential interactions due to urinary alkalinisation may occur with amphetamines, quinidine, ephedrine, fluoroquinolone antibiotics, mexiletine, and salicylates.

Sodium containing antacids, such as CLICKS ALGINIC ANTACID SUSPENSION, may increase the renal clearance of acidic medicines, such as salicylates and barbiturates.

PREGNANCY AND LACTATION

CLICKS ALGINIC ANTACID SUSPENSION may be used during pregnancy, but under supervision of a doctor (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years

Take two to four medicine measures (10 to 20 mL), after meals and at bedtime. Eighty (80) mL (16 medicine measures) should be the maximum dosage per day (24 hour period).

Children between 6 and 12 years:

Take two medicine measures (10 mL) after meals and at bedtime.

Forty (40) mL (8 medicines measures) should be the maximum dosage per day (24 hour period).

SIDE EFFECTS:

Calcium carbonate:

Metabolism and nutrition disorders:

The following side effects have been reported and frequencies are unknown:

Metabolic alkalosis with large doses or in patients with renal insufficiency.

Gastrointestinal disorders:

Frequent: Chalky taste.

Less frequent: Constipation.

The following side effects have been reported and frequencies are unknown:

Faecal impaction.

Renal and urinary system disorders:

The following side effects have been reported and frequencies are unknown:

Hypercalcaemia associated with milk-alkali syndrome may occur with large doses of calcium carbonate and/or in patients with chronic renal failure.

General disorders and administrative site conditions:

The following side effects have been reported and frequencies are unknown:

Swelling of the feet or lower legs.

Sodium bicarbonate:

Metabolism and nutrition disorders:

The following side effects have been reported and frequencies are unknown:

Excessive administration of sodium bicarbonate may lead to hyperkalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include muscle weakness, shortness of breath, tiredness, mood changes and irregular heartbeat.

Cardiac disorders:

The following side effects have been reported and frequencies are unknown:

Congestive heart failure may occur due to excessive sodium absorption.

Gastrointestinal disorders:

Less frequent: Increased thirst, stomach cramps.

The following side effects have been reported and frequencies are unknown:

Belching and flatulence.

Sodium alginate

No side effects have been reported with the use of sodium alginate.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

A feeling of abdominal distension may occur with very large doses of CLICKS ALGINIC ANTACID SUSPENSION.

Treatment is symptomatic and supportive.

IDENTIFICATION

Opaque off-white to cream suspension with peppermint flavour.

PRESENTATION

Carton containing light weight amber coloured glass bottles enclosed by white coloured plastic caps containing 100 mL or 200 mL suspension.

STORAGE INSTRUCTIONS

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

Keep the bottle in carton until required for use.

Keep well closed.

Shake the bottle.

Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

45/11.10/0040

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

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

27 July 2017