ALGIDUO

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for Algiduo (Alginate Raft-Forming Oral Suspension B.P.)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: 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 gastro-oesophageal 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.

INDICATIONS: It is indicated for the treatment of heartburn and Indigestion.

DOSAGE AND ADMINISTRATION: Adults and children 12 years and over: 5 -10ml. Children under 12 years: Should be given only on medical advice. Elderly: no dose modification is required in this age group. It should be given after meals and at bedtime.

CONTRAINDICATION: This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipients listed

WARNINGS & PRECAUTIONS: Algiduo should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 2 weeks if symptoms persist. If symptoms do not improve after seven days, the clinical situation should be reviewed. This medicinal product contains 286.5 mg (12.45 mmol) sodium per 20 ml dose, equivalent to 14.3 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 57.2 % of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment). 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. Algiduo should not be used by patients allergic to any of its constituents. Ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoates (E216) and butyl parahydroxybenzoate: may cause allergic reactions (possibly delayed).

DRUG INTERACTIONS: A time-interval of 2 hours should be considered between Algiduo Liquid 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 bisphosphonates (diphosphonates) and estramustine. 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.

ADVERSE REACTIONS: Anaphylactic and anaphylactoid reactions, hypersensitivity reactions such as urticarial, respiratory effects such as bronchospasm, diarrhoea, nausea and vomiting

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)