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

ALGIDUO

(Sodium alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension**)**

1. Generic Name

Sodium alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension

2. Qualitative and quantitative composition

Each 5 ml contains:

Sodium Alginate I.P. ……250 mg

Sodium Bicarbonate I.P. …...133.5 mg

Calcium Carbonate I.P. …….80 mg

Flavoured base……....q.s.

The excipients used are Methyl Paraben, Propyl Paraben, Disodium Edetate, Saccharin Sodium, Sorbitol, Carbomer Homo, Polysorbate-80, Colloidal Silicon Dioxide, Sodium Hydroxide Pellets, Menthol, Propylene Glycol, Citric Acid Monohydrate, Flavour Mint.

3. Dosage form and strength

Dosage form: Oral suspension

Strength: Sodium Alginate I.P. 250 mg, Sodium Bicarbonate I.P. 133.5 mg, Calcium Carbonate I.P. 80 mg

4. Clinical particulars

4.1 Therapeutic indication

Indicated for the treatment of heartburn and Indigestion.

4.2 Posology and method of administration

Posology

For oral administration

Adults and children over 12 years: Two to four 5 ml spoonful.

Doses should be taken after meals and at bedtime.

Children under 12 years: Should be given only on medical advice.

Elderly: No dosage modification is required in this age group.

Hepatic Impairment: No dose modification necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

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).

4.5 Drugs 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.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy:

Reported clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing experience indicate no malformative nor foeto/neonatal toxicity of the active substances. ALGIDUO 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. ALGIDUO 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 ALGIDUO 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 use machines.

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.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

4.9 Overdose

Symptoms

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

Management

In the event of overdose symptomatic treatment should be given.

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

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.

5.2 Pharmacokinetic properties

Alginic acid is not absorbed into the systemic circulation.

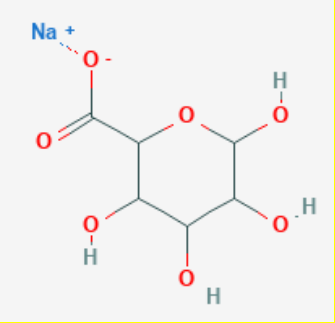
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

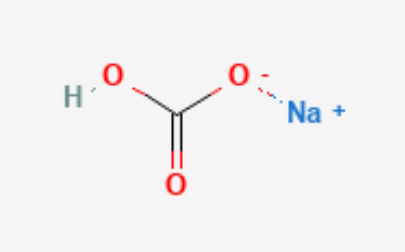
No preclinical data available.

7. Description

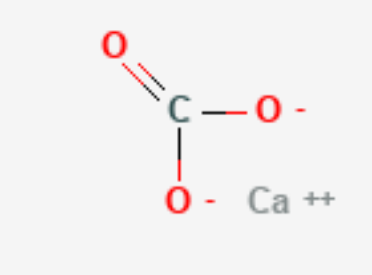
Sodium alginate is sodium;3,4,5,6-tetrahydroxyoxane-2-carboxylate. The empirical formula is $C_6H_9NaO_7$ and its molecular weight is 216.12 g/mol. The chemical structure of Sodium alginate is:



Sodium bicarbonate is sodium;hydrogen carbonate. The empirical formula is $NaHCO_3$ and its molecular weight is 84.007 g/mol. The chemical structure of Sodium bicarbonate is:



Calcium carbonate is calcium;carbonate. The empirical formula is $CaCO_3$ and its molecular weight is 100.09 g/mol. The chemical structure of Calcium carbonate is:



Sodium alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension is white to off white colored suspension. The excipients used are Methyl Paraben, Propyl Paraben, Disodium Edetate, Saccharin Sodium, Sorbitol, Carbomer Homo, Polysorbate-80, Colloidal Silicon Dioxide, Sodium Hydroxide Pellets, Menthol, Propylene Glycol, Citric Acid Monohydrate, Flavour Mint.

8. Pharmaceutical particulars

8.1 Incompatibilities

None Stated

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

ALGIDUO Oral Suspension is bottle pack of 150 ml.

8.4 Storage and handing instructions

Do not store above 30°C.

Keep out of reach of children

9. Patient Counselling Information

ALGIDUO

Sodium alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

9.5. How to store ALGIDUO

9.6. Contents of the pack and other information

9.1 What ALGIDUO is and what it is used for

Algiduo contains active ingredients Sodium alginate, Sodium Bicarbonate & Calcium Carbonate. Indicated for the treatment of heartburn and Indigestion.

How ALGIDUO works

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.

9.2 What you need to know before you use ALGIDUO

Before taking ALGIDUO, tell your doctor about all your medical conditions.

Tell your doctor, if you are allergic to **ALGIDUO** or any of the other ingredients of this medicine.

Warnings and 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).

Children and adolescents

Adults and children over 12 years:

Take 10-20 ml (two to four 5 ml spoonful's) after meals

and at bedtime, up to four times a day.

Children under 12 years:

Should be given only on medical advice.

Other medicines and ALGIDUO

Do not take this product within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines. This is especially important if you are taking antibiotics (tetracyclines and quinolones such as norfloxacin), iron preparations, antifungals such as ketoconazole, digoxin and beta blockers (for heart conditions), penicillamine (for rheumatoid arthritis), glucocorticoids (for inflammatory and autoimmune disorders), neuroleptics (for mental illness), thyroid hormones, chloroquine for malaria), estramustine (for prostate cancer), bisphosphonates (for osteoporosis), ACE inhibitors (for high blood pressure), analgesics (for pain relief), antiepileptics, antipsychotics and lithium (for mental health problems).

Pregnancy and breast-feeding

This product is sugar free. You can take this product if you are pregnant or breast-feeding.

Driving and using machines

There are no effects on ability to drive or use machines.

9.3 How to take ALGIDUO

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you take too much ALGIDUO than you should

If you take too much of this product you may feel bloated and experience some abdominal discomfort. It is unlikely to cause any harm, but please consult your doctor or pharmacist.

If you forget to take ALGIDUO

If you forget a dose it is not necessary to double the dose next time, just carry on taking as before

If you stop taking ALGIDUO

Do not stop taking ALGIDUO unless your doctor tells you to. If you have questions about how long to take this medicine, talk to your doctor.

9.4 Possible Side Effects

Very rarely (less than 1 in 10,000 patients treated) an allergic reaction to the ingredients may occur. Symptoms of this may include skin rash, difficulty in breathing, dizziness or swelling of the face, lips, tongue or throat. If you experience these or any side effects stop taking the product and consult your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting.

9.5 How to store ALGIDUO

Do not store above 30°C.

9.6 Contents of the pack and other information:

Sodium alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension is bottle pack of 150 ml.

The active substances are Sodium alginate, Sodium Bicarbonate & Calcium Carbonate

Each 5 ml of this medicine contains Sodium Alginate I.P. 250 mg, Sodium Bicarbonate I.P. 133.5 mg, Calcium Carbonate I.P. 80 mg

The excipients used are Methyl Paraben, Propyl Paraben, Disodium Edetate, Saccharin Sodium, Sorbitol, Carbomer Homo, Polysorbate-80,Colloidal Silicon Dioxide, Sodium Hydroxide Pellets, Menthol, Propylene Glycol, Citric Acid Monohydrate, Flavour Mint.

10 Details of manufacturer

Akums Drugs & Pharmaceuticals Ltd.
Plot No. 22, Sec-6A, IIE,
SIDCUL, Ranipur,
Haridwar – 249403.

11 Details of permission or licence number with date

Mfg Licence No.: 123/UA/2007 issued on 23.03.2022

12 Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ ALGIDUO/Nov-22/01/PI