SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE PRODUCT

Lagita® Double Action (Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate) Suspension 500mg + 213mg + 325mg

Sugar Free

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lagita® Double Action Suspension 500mg + 213mg + 325mg
Each 10ml contains:
Sodium Alginate BP.....500mg
Sodium Bicarbonate BP.....213mg
Calcium Carbonate BP.....325mg

3. PHARMACEUTICAL FORM

Suspension.

Appearance: Cream to off-white homogenous suspension.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS:

Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION:

For oral administration:

- **Adults and children 12 years and over:** 10-20ml after meals and at bedtime, up to four times per day.
- **Children under 12 years:** Should be given only on medical advice.
- **Elderly:** No dose modifications necessary for this age group.
- **Hepatic Impairment:** No dose modification necessary.
- **Renal Insufficiency:** Caution if highly restricted salt diet is necessary.

4.3. CONTRAINDICATIONS:

Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients. This product should not be used in patients with moderate or severe renal insufficiency.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- This medicinal product contains 144mg sodium per 10ml dose, equivalent to 7.2% of the WHO recommended maximum daily intake for sodium.
- The maximum daily dose of this product is equivalent to 57.6% 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 20ml contains 260mg (6.5mmol) of calcium. Care needs to be taken in treating patients with hypercalcemia, nephrocalcinosis and recurrent calcium containing renal calculi.
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.
- If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought.
- As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions.
- Contains methyl parahydroxybenzoate (E218) 40mg/10ml and propyl parahydroxybenzoate (E216) 6mg/10ml which may cause allergic reactions (possibly delayed).

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

Due to the presence of calcium and carbonates which act as an antacid, a time-interval of 2 hours should be considered between intake of this product and the administration of other medicinal products, especially H2-antihistaminics, tetracyclines, digoxin, fluoroquinolones, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, diphosphonates, and estramustine.

4.6. FERTILITY, PREGNANCY AND LACTATION:

Fertility:
Does not affect human fertility.
Pregnancy:
It can be used during pregnancy, if clinically needed.
Breast-feeding:
It can be used during breast-feeding if clinically needed.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

This product has no or negligible influence on the ability to drive and use machines.

4.8. UNDESIRABLE EFFECTS:

Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: 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); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Very Rarely	Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not Known	Alkalosis[1], acid rebound[1], hypercalcaemia[1], milk-alkali syndrome[1]
Respiratory, Thoracic and Mediastinal Disorders	Very Rarely	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Not Known	Constipation[1]

Description of Selected Adverse Reactions:
[1] Usually occurs following larger than recommended dosages.

4.9. OVERDOSE:

Symptoms:
Symptoms are likely to be minor in acute overdose; some abdominal distension may be noticed. Milk-alkali syndrome has occurred in individuals taking large doses of calcium carbonate per day for prolonged periods.
Management:
In the event of overdosage symptomatic treatment should be given.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES:

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease, **ATC code:** A02BX.
Mechanism of action:
The medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate. On ingestion, the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and studies have shown that the raft interacts with and caps the acid pocket in the stomach, reducing oesophageal acid exposure. The raft floats on the stomach contents effectively impeding gastro-oesophageal reflux, for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect. In addition, in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within its structure, further protecting the oesophagus from these gastric components. Calcium carbonate neutralizes gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralizing action. The total neutralizing capacity of the product at the lowest dose of two tablets is approximately 10mEqH+.

5.2. PHARMACOKINETICS:

The mode of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3. PRECLINICAL SAFETY DATA:

No pre-clinical findings of any relevance to the prescriber have been reported.

SUMMARY OF PRODUCT CHARACTERISTICS

6. PHARMACEUTICAL PROPERTIES

6.1. LIST OF EXCIPIENTS:

- Carbomer 974P
- Methyl paraben
- Propyl paraben
- Sodium saccharin
- Sodium hydroxide
- Peppermint oil
- Purified water

6.2. INCOMPATIBILITIES:
Not applicable.

6.3. SHELF LIFE:
See expiry on the pack.

6.4. SPECIAL PRECAUTIONS FOR STORAGE:
Do not store over 30°C, and protect from heat, light and freezing. Improper storage may deteriorate the medicine.
Keep out of reach of children.
Use within six months of opening.

6.5. NATURE AND CONTENTS OF CONTAINER:
Amber glass bottle with tamper-proof aluminium cap with P.E. wad, bottle size is 120ml.

6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:
No special requirement.

6.7. DRUG PRODUCT SPECIFICATIONS:
BP Specs.

7. MARKETING AUTHORISATION HOLDER

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com
Mfg. Lic. No. 000072

8. MARKETING AUTHORISATION NUMBER(S)

103095

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st August, 2020

10. DATE OF REVISION OF THE TEXT

لجیٹا® ڈبل ایکشن سسپینشن

(سوڈیم الجینیٹ + سوڈیم بائی کاربونیٹ + کیلشیم کاربونیٹ)

ہدایات:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،

گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں ورنہ دوا خراب ہو جائیگی۔

دوا کھولنے کے بعد ۶ مہینے کے اندر استعمال کریں۔