Lagita® Advance

(Sodium Alginate + Potassium Bicarbonate)

1. NAME OF THE PRODUCT

Lagita® Advance (Sodium Alginate + Potassium Bicarbonate) Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lagita® Advance Suspension

Each 10ml of suspension contains:
Sodium Alginate BP.....1g
Potassium Bicarbonate BP.....200mg

3. PHARMACEUTICAL FORM

Oral suspension

Appearance:
Off-white to cream colored, viscous suspension having characteristic odor.

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, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy, accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throat and cough.
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:

Adults and children 12 years and over: 5-10ml after meals and at bedtime or as prescribed by the physician.
Children under 12 years: Should be given only on medical advice.
Elderly: No dose modification is required for 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 or any of the excipients listed.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

For Sodium alginate + Potassium bicarbonate suspension:

This medicinal product contains 53.43mg sodium per 5ml, equivalent to 2.67% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 21.40% 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.

Potassium: This medicine contains 1.02mmol (40.02mg) potassium per 5ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Each 10ml contains 200mg (2.0mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxy-benzoate (E216): May cause allergic reactions (possibly delayed).

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

A time-interval of 2 hours should be considered between sodium alginate + potassium bicarbonate intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

4.6. FERTILITY, PREGNANCY AND LACTATION:

Fertility: No known effect on human fertility.

Pregnancy: Can be used during pregnancy, if clinically needed.

Breast-feeding: No known effect on breast fed infants; can be used during breast-feeding.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

None.

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 < 1/10,000) and not known (cannot be estimated from the available data).

The following adverse reactions reported.

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.
Gastrointestinal Disorders	Uncommon	Diarrhoea, nausea, vomiting.

4.9. OVERDOSE:

Symptoms: Symptoms are likely to be minor; some abdominal discomfort may be experienced.

Management: In the event of overdose, symptomatic treatment should be given.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES:

Pharmacotherapeutic classification: Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

ATC Code: A02BX 13.

On ingestion, the drug reacts with gastric acid to rapidly form a raft of alginic acid gel having a near-neutral pH which 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.

5.2. PHARMACOKINETIC PROPERTIES:

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

5.3. PRECLINICAL SAFETY DATA:

There are no preclinical findings of reference to the prescriber, which are additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS:

- Calcium carbonate

- Methyl paraben
- Propyl paraben
- Sodium saccharin
- Neotame powder
- Acesulfame-K
- Methocel
- Carbomer
- Xanthan gum
- Peppermint oil
- Anise oil
- Distilled water
- 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 and freezing.
Improper storage may deteriorate the medicine.
Keep out of reach of children.

6.5. NATURE AND CONTENTS OF CONTAINER:
Amber glass bottle with tamper-proof aluminum 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. REGISTRATION / MARKETING AUTHORISATION HOLDER

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

8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)
076759

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

24th March, 2015

10. DATE OF REVISION OF THE TEXT

لَجِیٹا® ایڈوانس سسپینشن

(سوڈیم الجینیٹ + پوٹاشیم بائی کاربونیٹ)

ہدایات:

خوراک: 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 اور منجمد ہونے سے محفوظ رکھیں ورنہ دوا خراب ہو جائیگی۔