23-12-2022
2nd Copy

Change due to Storage Condition

210mm

Lagita® Advance Suspension / Chewable Tablets

(Sodium Alginate + Potassium Bicarbonate)

Sugar Free

QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Lagita® Advance Chewable Tablets
Each chewable tablet contains:
Sodium Alginate BP.....500mg
Potassium Bicarbonate BP.....100mg

PHARMACEUTICAL FORM

Suspension/Chewable tablet.

CLINICAL PARTICULARS

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.

POSOLOGY AND METHOD OF ADMINISTRATION:
Suspension:
Adults and children 12 years and over: 5-10ml after meals and at bedtime or as prescribed by the physician.

Chewable Tablets:
For oral administration, after being thoroughly chewed.
Adults and children 12 years and over: One to two tablets after meals and at bedtime or as prescribed by the physician.

Suspension/Tablets:
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.

CONTRAINDICATIONS:
Contraindicated in patients with known or suspected hypersensitivity.

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 112.37mg (5.30mmol) sodium per 10ml dose, equivalent to 5.62% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 22.262% 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).

This medicine contains 81mg (2.1mmol) potassium per 10ml dose. 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 parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).

For sodium alginate + potassium bicarbonate chewable tablets:
This medicinal product contains 53.22mg sodium per tablet, equivalent to 2.7% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 21.28% 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. insome cases of congestive heart failure and renal impairment).

This medicine contains 39.83mg (1.01mmol) potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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

This medicine contains 10.60mg aspartame (E951) in each tablet. Aspartame (E951) is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU).

May cause central nervous system depression in the presence of renal insufficiency and should not be used in patients with renal failure.

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.

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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
None.

120mm

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UNDESIRABLE EFFECTS:
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.

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

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:
Suspension:
Pharmacotherapeutic classification: Anti-regurgitant. **ATC code:** A02E A01.

Chewable Tablet:
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.

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

SHELF LIFE

See expiry on the pack.

AVAILABILITY

Lagita®Advance suspension in a pack of 150ml.
Lagita®Advance chewable tablets in a pack of 48's.

INSTRUCTIONS

Dosage: As directed by the physician.
To be sold on the prescription of a registered medical practitioner only.
Keep out of reach of children.
For Chewable Tablets: Avoid exposure to heat, light and humidity. Store between 15 to 30°C.
For Suspension: Do not store over 30°C, and protect from heat and freezing.
Improper storage may deteriorate the medicine.

لگیٹا® ایڈوانس سسپینشن/چیوایبل ٹیبلٹ

(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۔
برائے چیوایبل ٹیبلٹ: دوا کو گرمی، روشنی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں۔
برائے سسپینشن: 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۔

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com
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120mm