ACIDEX® 120 ml

SUSPENSION

(Sodium Alginate + Potassium Bicarbonate)

ایسی ڈیکس ۱۲۰ ملی لیٹر

سسپنشن

COMPOSITION:

Each 10ml contains:

Sodium Alginate (USP) 1000mg

Potassium Bicarbonate (B.P) 200mg

Product complies as per *Innovators Specs.

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 throats 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

Adults and children 12 years and over:

5-10 ml after meals and at bedtime.

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

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

Special warnings and precautions for use

If symptoms do not improve after 7 days, the clinical situation should be reviewed. This medicinal product contains 106 mg (5.0 mmol) sodium per 10 ml dose, equivalent to 5.3% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 21% 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).

Potassium: This medicine contains 78 mg (2.0 mmol) potassium per 10 ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Interaction with other medicinal products and other forms of interaction
A time-interval of 2 hours should be considered between ACIDEX intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

Fertility, pregnancy and lactation
Pregnancy:
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. Acidex can be used during pregnancy, if clinically needed.

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

Fertility:
No known effect on human fertility.

Effects on ability to drive and use machines:
None

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	Frequecny	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.

OVERDOSAGE:
Symptoms
Symptoms are likely to be minor; some abdominal discomfort may be experienced.
Management
In the event of overdose, symptomatic treatment should be given.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties:
Pharmacotherapeutic classification: Anti-regurgitant
On ingestion the suspension 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 it structure, further protecting the oesophagus from these gastric components.

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

Shelf life
Two years.

STORAGE CONDITIONS AND OTHER INFORMATION:
• Keep out of the sight and reach of children.
• Do not store above 30°C.
• Do not refrigerate. Keep the bottle upright.
• Do not use after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of the month.
Medicines should not be disposed of via wastewater or household waste.

PRESENTATION:
Acidex suspension is available in pack size of 120ml.

ہدایات:
- **خوراک** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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