

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Acidex Oral Suspension

LloydsPharmacy Heartburn and Indigestion Liquid Peppermint Flavoured

Boots Heartburn Relief Peppermint Flavour

Peptac Peppermint Liquid

Tesco Heartburn & Indigestion relief

Heartburn and Indigestion Oral Suspension Peppermint Flavour

Healthpoint Heartburn and Indigestion Oral Suspension

Rennie Liquid Heartburn Relief Oral Suspension

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5ml contains:

Sodium Bicarbonate PhEur - 133.5mg

Sodium Alginate PhEur - 250mg

Calcium Carbonate PhEur - 80mg

### **3 PHARMACEUTICAL FORM**

Oral Suspension

Peppermint Flavoured White Suspension

Gluten and Sugar free

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Acidex alleviates the painful conditions resulting from the reflux of gastric acid and bile into the oesophagus by suppressing the reflux itself. It is indicated in heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia, reflux oesophagitis, regurgitation and all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

#### **4.2 Posology and method of administration**

For oral use

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

Children 6 -12 years: One to two 5ml spoonfuls

Not recommended in children under six years of age.

Doses should be taken after meals and at bedtime.

#### **4.3 Contraindications**

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients listed in section 6.1, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) (see section 4.4).

#### **4.4 Special warnings and precautions for use**

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

Each 10 ml dose of Acidex contains about 6 mmoles of sodium and therefore care should be exercised in patients on a sodium restricted diet.

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.

Acidex should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 2 weeks if symptoms persist.

Acidex should not be used by patients allergic to any of its constituents.

Parahydroxybenzoates (E214, 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 Acidex 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 biphosphonates (diphosphonates) and estramustine. See also 4.4.

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 Pregnancy and lactation**

##### **Pregnancy:**

Clinical studies in more than 500 pregnant women as well as a large amount of data from postmarketing experience indicate no malformative nor feto / neonatal toxicity of the active substances. Acidex 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. Acidex 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 Acidex 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 operate machinery.

#### **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).

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Event</b>
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.

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#### **4.9 Overdose**

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

## **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 gastrooesophageal 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.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Carbomer  
Sodium Hydroxide  
Saccharin Sodium  
Ethyl parahydroxybenzoate (E214)  
Propyl parahydroxybenzoate (E216)  
Butyl parahydroxybenzoate  
Isopropyl Alcohol  
Peppermint Oil  
Purified Water

### **6.2 Incompatibilities**

None known.

**6.3 Shelf life**

24 months - amber glass bottles

18 months - HDPE bottles

12 months - PET bottles

**6.4 Special precautions for storage**

Do not store above 25°C. Do not refrigerate or freeze.

**6.5 Nature and contents of container**

Pharmaceutical Grade III amber glass bottles with pilfer proof caps and tamper evident screw caps.

High density polyethylene bottles with tamper evident screw caps.

PET bottles with tamper evident screw caps.

Pack sizes: 100ml, 150ml, 200ml, 250ml, 300ml and 500ml.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

Not applicable

**7 MARKETING AUTHORISATION HOLDER**

Pinewood Laboratories Limited

Ballymacarbry

Clonmel

Co. Tipperary

Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 04917/0027

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

09/07/2002 / 26/03/2009

**10 DATE OF REVISION OF THE TEXT**

01/02/2018