

## Acidex Advance Oral Suspension (Aniseed Flavour)

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1 NAME OF THE MEDICINAL PRODUCT

Acidex Advance Oral Suspension (Aniseed Flavour)

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:

Sodium Alginate 1000 mg

Potassium hydrogen carbonate 200 mg

Excipients include:

Ethyl parahydroxybenzoate (E214) 15.0 mg/10 ml

Propyl parahydroxybenzoate (E216) 5.50 mg/10 ml

Butyl parahydroxybenzoate 2.50 mg/10 ml

For a full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Oral Suspension,

Aniseed flavoured white or cream coloured 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, 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.

##### 4.2 Posology and method of administration

Adults and children 12 years and over: 5 -10ml after meals and at bedtime

Children under 12 years: Should be given only on medical advice.

Elderly: no dose modification is required in this age group.

### **4.3 Contraindications**

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipients listed in section 6.1, including the esters of hydroxybenzoates (Parabens) (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 contains about 5.1mmol of sodium and 2mmol of potassium. This should be taken into account when a highly restricted salt diet is recommended, e.g in some cases of congestive cardiac failure and renal impairment or when taking drugs which can increase potassium levels.

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

Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)

### **4.5 Interaction with other medicinal products and other forms of interaction**

None

### **4.6 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 Advance can be used during pregnancy, if clinically needed.

#### **Breast feeding:**

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

#### **Fertility**

No known effect on human fertility.

### **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 ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $< 1/10$ ), uncommon ( $\geq 1/1000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1, 1000$ ), very rare ( $< 1/10,000$  cases), and not known (cannot be estimated from the available data).

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.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

#### 4.9 Overdose

In the event of overdosage, symptomatic treatment should be given. The patient may notice abdominal distension.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

ATC Code: A02BX13

Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

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 its structure, further protecting the oesophagus from these gastric components.

#### 5.2 Pharmacokinetic properties

The mode of action of the product is physical and does not depend on absorption 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**

Calcium Carbonate

Carbomer

Sodium Hydroxide

Saccharin Sodium

Ethyl Parahydroxybenzoate (E214)

Propyl Parahydroxybenzoate (E216)

Butyl Parahydroxybenzoate

Isopropyl Alcohol

Star Anise Oil

Purified Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

24 months

Use within 3 months of opening

### **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 Type III amber glass bottles with white polypropylene caps that have a Low density Polyethylene (LDPE) liner

Pack sizes: 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**

Wockhardt UK Ltd

Ash Road North

Wrexham

LL13 9UF

UK.

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 29831/0697

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

28/09/2016

**10     DATE OF REVISION OF THE TEXT**

28/01/2019

## Acidex Advance Oral Suspension (Peppermint Flavour)

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1 NAME OF THE MEDICINAL PRODUCT

Acidex Advance Oral Suspension (Peppermint Flavour)

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:

Sodium Alginate 1000 mg

Potassium hydrogen carbonate 200 mg

Excipients include:

Ethyl parahydroxybenzoate (E214) 15.0 mg/10 ml

Propyl parahydroxybenzoate (E216) 5.50 mg/10 ml

Butyl parahydroxybenzoate 2.50 mg/10 ml

For a full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Oral Suspension,

Peppermint flavoured white or cream coloured 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, 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.

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Each 10 ml dose contains about 5.1mmol of sodium and 2mmol of potassium. This should be taken into account when a highly restricted salt diet is recommended, e.g in some cases of congestive cardiac failure and renal impairment or when taking drugs which can increase potassium levels.

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

Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)

### **4.5 Interaction with other medicinal products and other forms of interaction**

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### **4.6 Fertility, Pregnancy and lactation**

#### **Pregnancy:**

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#### **Breast feeding:**

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

#### **Fertility**

No known effect on human fertility.

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