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.

This medicinal product contains 106 mg (5.1mmol) 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 cardiac 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.

Each 10 ml 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.

Contains 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 Advance 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

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 (≥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 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.
Gastrointestinal disorders	Uncommon	Diarrhoea Nausea Vomiting

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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 quickly and 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.

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

30/01/2025

10 DATE OF REVISION OF THE TEXT

30/01/2025