Abbreviated Prescribing Information: Acidex Advance Oral Suspension (Aniseed Flavour or Peppermint Flavour) 250ml and 500ml, (Sodium Alginate 1000mg/10ml, Potassium hydrogen carbonate 200mg/10ml). Please refer to the Summary of Product Characteristics (SmPC) before prescribing

PRESENTATION: Oral Suspension, Aniseed or Peppermint flavoured, white or cream coloured suspension. **INDICATIONS:** For 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. **DOSAGE AND 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. **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 of the SmPC, including the esters of hydroxybenzoates (Parabens). **WARNINGS AND PRECAUTIONS:** If symptoms do not improve after seven days, the clinical situation should be reviewed. Each 10ml 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 200mg (2.0mmol) 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). **DRUG INTERACTIONS:** None. **PREGNANCY AND LACTATION:** Clinical studies 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. There is no known effect on breast fed infants. Acidex Advance can be used during breast feeding. **UNDESIRABLE EFFECTS:** The following adverse events were reported in clinical practice: Very rare (<1/10,000 cases): Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria. Respiratory effects such as bronchospasm. For further information on adverse effects please refer to the SmPC. **LEGAL CATEGORY:** P **MARKETING AUTHORISATION NUMBER AND HOLDER:** Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland. **Marketing Authorisation Number:** PL 04917/0143 and PL 04917/0144 **PACKAGE QUANTITIES AND BASIC NHS PRICE:** Acidex Advance oral suspension Aniseed Flavour 250ml: £1.92, 500ml: £3.84; Acidex Advance oral suspension Peppermint Flavour250ml: £1.92, 500ml: £3.84
DATE OF API PREPARATION: 17/12/2018

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Wockhardt UK Ltd by calling: +44 (0) 1978 669272 or email drug.safety@wockhardt.co.uk