

Acepiro® 600 mg effervescent tablets – Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Acepiro® 600mg effervescent tablets.

Each tablet contains 600 mg acetylcysteine. **Uses** Acepiro® is indicated in adults as a mucolytic agent for the treatment of respiratory tract diseases in which a reduction in bronchial secretion viscosity is required to facilitate expectoration. **Dosage and Administration** One tablet daily after food. Each tablet should be dissolved in half a glass of water. Duration of therapy should be determined by the treating physician. **Special Warnings and Precautions** Hypersensitivity to the active substance or to any of the excipients. Acepiro® should not be used by adolescents or children. Use with caution in patients with a history of asthma or bronchospasm. Should bronchospasm occur Acepiro® should be discontinued immediately. Very rarely, serious skin reactions such as Stevens-Johnson syndrome and Lyell syndrome have been reported. Patients should be advised to seek immediate medical advice in the presence of new skin or mucosal lesions. Administer with caution in patients with a reduced cough reflex for example elderly or frail patients. Postural drainage and broncho-aspiration should be performed in patients unable to cough up bronchial secretions effectively. Incompletely dissolved tablets present a risk of choking and aspiration, particularly to elderly patients. Use with caution in patients with a history of peptic ulcer disease or histamine intolerance. Hepatic and renal impairment can reduce clearance and increase systemic acetylcysteine plasma levels which may result in an increase in adverse drug reactions due to drug accumulation. **Contraindications** Hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Interactions with other medicinal products** In vitro tests indicate that tetracycline, aminoglycosides and penicillin are inactivated when mixed directly with acetylcysteine. Where concomitant use of Acepiro® and oral antibiotics is required, separate administration by an interval of at least two hours. Acetylcysteine may potentiate the vasodilatory effect of nitroglycerine. Do not administer concurrently with antitussives. Acetylcysteine may reduce the bioavailability of certain heavy metal salts and should be taken separately at different times of the day. **Pregnancy fertility and Lactation** Administration of acetylcysteine during pregnancy and lactation should take place only after a strict risk benefit assessment. **Side Effects** The following events have been reported by at least one in a thousand and less than one in a hundred patients treated with acetylcysteine – hypersensitivity reactions, headache, tinnitus, tachycardia, stomatitis, abdominal pain, nausea, vomiting, diarrhoea, pruritus, urticaria, exanthema, rash, angioedema, pyrexia and lowered blood pressure. The incidence of facial oedema has not been established. **Overdose** There have been no reports of toxic overdose with oral acetylcysteine. In the case of an overdose of Acepiro®, management should be supportive. **Effects on the ability to drive and/or operate machines** Acepiro® has no effect on the ability to drive or operate machines **Legal category:** POM **Pack size:** 20 or 30 effervescent tablets in strips of laminated aluminium paper foil. **Shelf life:** 3 years. **NHS price:** 20 effervescent tablets = £3.65 30 effervescent tablets = £5.25 **Marketing Authorisation Holder:** Stirling Anglian Pharmaceuticals Ltd, Hillington Park Innovation Centre, 1 Ainslie Road, Hillington Park, Glasgow G52 4RU **Marketing Authorisation Number:** PL 42582/0015

Further information is available at medinfo@stirlinganglianpharmaceuticals.com or via the office number **0345 527 0680** **Date of preparation:** 14 August 2025

Adverse events should be reported. Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk> or downloaded from Google Play or the Apple App store. Adverse events should also be reported to JensonR+ on **01271 334609** or Stirling Anglian Pharmaceuticals on **0345 527 0680**.

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