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, rurritus, 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 = £4.40

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: 17 October 2024 Unique Code: 24-API-002 v1.0

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 334 609 or Stirling Anglian Pharmaceuticals on 0345 527 0680.

References

- Acepiro SmPc available at https://www.medicines.org. uk/emc/product/13849. Date accessed November 2024
- Mucodyne SmPc available at https://www.medicines. org.uk/emc/product/2916. Date accessed November 2024
- 3. The effect of oral N-acetylcysteine in chronic bronchitis: a quantitative systematic review. C. Stey et al. Eur Respir J 2000;16:253±262
- Systematic review and meta-analysis of the efficacy of N-acetylcysteine in the treatment of acute exacerbation of chronic obstructive pulmonary disease. Caiyu Jiang et al. Ann Palliat Med 2021;10(6):6564-6576
- Role of N-acetylcysteine in the management of COPD. Anna M Sadowska et al. Therapeutics and Clinical Risk Management 2006:2(1) 3–18
- NICE guideline [NG115]. Chronic obstructive pulmonary disease in over 16s: diagnosis and management. Available at https://www.nice.org.uk/guidance/NG115. Date accessed November 2024
- Drug tariff available at https://www.drugtariff.nhsbsa. nhs.uk/#/00833627-DD/DD00833624/Home. Date accessed November 2024
- 8. BNF Nacsys available at https://bnf.nice.org.uk/drugs/acetylcysteine/medicinal-forms/#effervescent-tablet.
 Date accessed November 2024
- Nacsys SmPc available at https://www.medicines.org. uk/emc/product/8576. Date accessed November 2024

Acepiro 600 mg Effervescent Tablets Acetylcysteine







Reliable supply and distribution in the UK quaranteed



Prescribe Acepiro® by brand

> Save between 13% and 79% compared to carbocisteine*7

> > Save at least 20% compared to other brand and generic acetylcysteine⁷

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 expectoration¹.

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Keep it simple





Each Acepiro® effervescent tablet dissolves easily in half a glass of water to form a lemon-flavoured solution which many patients find easier to take than swallowing tablets or capsules¹.

Why prescribe 6 carbocisteine* capsules when you can prescribe just one Acepiro®?

*Recommended starting dose for carbocisteine is 6 x 375mg capsules daily². †Compared to prescribing carbocisteine 375mg 6 capsules daily.

Effective







Improving lung function⁴



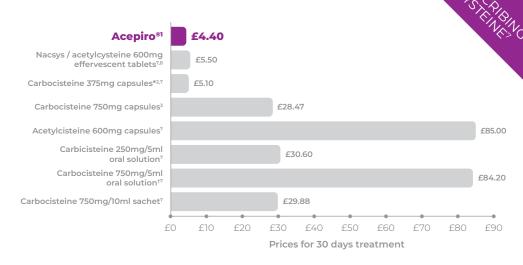
Reducing the risk of exacerbations³



Reducing the number of hospitalisation days⁵

66 Consider mucolytic drug therapy for people with a chronic cough productive of sputum⁶ **11**

Economical



Prescribe Acepiro® by brand and save between 13% and 79% compared to carbocisteine*7.

*Savings calculated on starting dose of 750mg three times daily between available products on the tariff².

Nacsys is indicated for use as a mucolytic in respiratory disorders such as in bronchitis, emphysema, mucoviscidoses and bronchiectasis in adults⁹.

†This cost applies only to the Drug Tariff for England Wales and Northern Ireland.



Prescribe Acepiro® by brand

