

## Abridged Prescribing Information

**Product name:** NACSYS 600mg effervescent tablets.

**Composition:** Each effervescent tablet contains 600mg of acetylcysteine, sodium hydrogen bicarbonate (E500) (equivalent to 115mg of sodium).

**Therapeutic Indication:** NACSYS is indicated for use as a mucolytic in adults with respiratory disorders.

**Posology:** One effervescent tablet of 600mg to be taken once daily.

**Method of Administration:** Dissolve NACSYS 600mg, effervescent tablets in half a glass of water to produce a solution that can be consumed immediately. Patients with a reduced cough reflex (elderly and weakened patients) are advised to take the tablet in the mornings.

**Contraindications:** Hypersensitivity to acetylcysteine or to any of the excipients. The tablets should not be used by children under two years of age.

**Special warnings and precautions:** Bronchospasm may occur with the use of NACSYS. Treatment with NACSYS should be discontinued immediately if this occurs. The administration of NACSYS may liquefy bronchial secretions and increase their volume. If the patient is unable to expectorate efficiently, postural drainage and bronchoaspiration should be used.

**Interactions:** Antitussive drugs and acetylcysteine should not be administered concomitantly; activated charcoal may reduce the effect of acetylcysteine; it is precautionary to advise the administration of oral antibiotics at least two hours before or after acetylcysteine; concurrent administration of acetylcysteine with nitro glycerine may enhance its vasodilatory effect. Acetylcysteine can interfere with the colorimetric assay for the determination of salicylates.

**Pregnancy & Lactation:** If necessary NACSYS 600mg may be used during pregnancy and lactation although there are limited data about its use.

**Undesirable effects:** Common (>1/100 ) undesirable effects have not been reported. Uncommon ( $\geq 1/1000$ , <1/100) Hypersensitivity headache; tinnitus; tachycardia; hypotension, gastrointestinal reaction (vomiting, diarrhoea, stomatitis, abdominal pain, nausea); fever. Rare ( $\geq 1/10000$  < 1/1000): dyspepsia; Very rare (<1/100000): anaphylactic shock, anaphylactic reaction, haemorrhage; Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have very rarely been reported in temporal connection with the use of acetylcysteine. Prescribers should consult the Summary of Product Characteristics in relation to other adverse effects.

**Reporting adverse effects:** Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Atlantic Pharma at [safety@atlanticpharma.co.uk](mailto:safety@atlanticpharma.co.uk) and 0845 5191 609

**NHS price:** £5.50 for a pack of thirty effervescent tablets.

**Legal classification:** POM

**Distributor:** Atlantic Pharma, 25a Becher Close, Renhold, MK41 OLP

**MA number:** PL 31388/0006

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