

Pharmaceutical Product

ACETYLCYSTEINE 600 MG effervescent tablets (aluminium-tubes)

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| Active Pharmaceutical Ingredient | Acetylcysteine |
| Indication | To liquefy mucus and to facilitate expectoration in bronchitis induced by a cold |
| ATC-Code | R05CB01 |
| Product USPs | <ul style="list-style-type: none"> – Easy expectoration, facilitation of respiration – Removes germs – Sparkling fresh, lemon flavour, no dyes, no sugar |
| Reference Product | Fluimucil® / Zambon |
| Strength | 600 mg |
| Dosage Form | Effervescent tablets White, flat, round tablet, breaking notch on one side, characteristic odour of acetylcysteine and lemon aroma, diameter 18 mm |
| Batch Size | 600 mg: 900 kg = 480,000 effervescent tablets |
| Primary Packaging | Aluminium tubes with PE stoppers containing a desiccant 600 mg: with 10 effervescent tablets |
| Secondary Pack Size | 600 mg: boxes of 10 effervescent tablets or a multiple thereof |
| Manufacturer | Aenova Site Temmler Pharma GmbH (DE) |
| Stability Data (ICH) | 600 mg: CZ II on 3 batches for 3 years CZ IVb on 3 batches for 1,5 years, ongoing target 3 years In-use stability: 6 months (in PP tubes) Shelf life: 3 years / CZ II; 1,5 years / CZ IVb Do not store above 30° C |
| Status Dossier | Modules 2-5 in EU-CTD available National German Marketing Authorizations available BE study is not required because the active substance is administered as solution |