

Pharmaceutical Product

ACETYLCYSTEINE 600 MG effervescent tablets (aluminium-tubes)

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)	<table border="0"> <tr> <td>600 mg:</td> <td>CZ II on 3 batches for 3 years</td> </tr> <tr> <td></td> <td>CZ IVb on 3 batches for 1,5 years, ongoing target 3 years</td> </tr> <tr> <td>In-use stability:</td> <td>6 months (in PP tubes)</td> </tr> <tr> <td>Shelf life:</td> <td>3 years / CZ II; 1,5 years / CZ IVb</td> </tr> <tr> <td colspan="2">Do not store above 30° C</td> </tr> </table>	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	
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	<p>Modules 2-5 in EU-CTD available</p> <p>National German Marketing Authorizations available</p> <p>BE study is not required because the active substance is administered as solution</p>										