

Bromhexine HCl 4 mg/5 ml oral solution
Bromhexine HCl 8 mg/5 ml oral solution
 Based on Maltitol syrup (without sorbitol)

Active ingredient	Bromhexine hydrochloride
Strength	4 mg/5 ml 8 mg/5 ml
Therapeutic indication	Common cold, influenza, infections of the respiratory tract or in other conditions associated with abnormal mucus secretion and impaired mucus transport.
Composition	Based on Maltitol syrup (similar to innovator product)
Reference (originator) product	Bisolvon oral solution 4 mg/5 ml Bisolvon oral solution 8 mg/5 ml
Pharmaceutical form	Oral solution
Pack Size	150 ml 250 ml
Packaging	Glass bottle with PE cap, and PP measuring cup
Finished product manufacturer	Basic Pharma Manufacturing – The Netherlands
Biostudy	No
Clinical trial	No
Regulatory status	Dossier format: e-CTD National registration in NL
Shelf-life	30 months
Batch size	750 – 3000 Liters

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