

Mometasone nasal spray

Active ingredient	Mometasone furoate monohydrate
Strength	50mcg per dose
Therapeutic indication	Nasal Spray for the treatment of symptoms of seasonal and perennial allergic rhinitis, and the treatment of nasal polyps
Reference (originator) product	Nasonex nasal spray suspension 50 microgram/ spray
Pharmaceutical form	Nasal spray suspension
Pack Size	60, 120 or 140 doses
Packaging	HDPE bottle
Finished product manufacturer	Basic Pharma Manufacturing – The Netherlands
Biostudy	No, an in-vitro bio-equivalence study is performed
Clinical trial	No
Regulatory status	Dossier format: e-CTD DCP application with NL as RMS. CMS countries: DK, SE.
Shelf-life	36 months
Batch size	800 kg

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