

Azelastine/Fluticasone nasal spray

Active ingredient	Fluticasone propionate Azelastine hydrochloride
Strength	137mcg/50mcg per dose (azelastine/fluticasone)
Therapeutic indication	Nasal spray for the treatment of symptoms of seasonal allergic rhinitis, providing effective relief of allergy symptoms
Reference (originator) product	Avamys 27,5 microgram /dose, nasal spray suspension
Pharmaceutical form	Nasal spray suspension
Pack Size	120 doses
Packaging	Amber glass 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: tbd.
Shelf-life	36 months
Batch size	250 kg - 800 kg

For any other information please contact:

Business Development
bd@basicpharma.nl

Burgemeester Lemmensstraat 352
 6163 JT Geleen
 Netherlands

+31(0)88 255 40 10
basicpharma.nl