

**MANUFACTURING GUIDE FOR
Azelastine Hydrochloride and Fluticasone Propionate Aqueous Nasal Spray
DUONASE**

LABEL CLAIM:

Each spray delivers :
Fluticasone propionate BP.....50 mcg
Azelastine Hydrochloride BP140 mcg

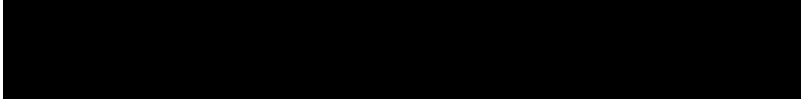
Composition :

Fluticasone propionate BP.....
Azelastine Hydrochloride BP
Benzalkonium chloride NF.....
(as preservative)
Phenyl ethyl alcohol USP.....
(as preservative)

BATCH SIZE : 100 KGS.

S.NO.	NAME OF INGREDIENTS	QUANTITY % w/v	QUANTITY/ BATCH (kgs)
1.	* Fluticasone propionate BP		
2.	** Azelastine Hydrochloride BP		
3.	Glycerin IP		
4.	Microcrystalline cellulose & carboxymethyl cellulose sodium USNF (Avicel RC-591)		
5.	Polysorbate 80 IP		
6.	Benzalkonium chloride NF		
7.	Phenyl ethyl alcohol USP		
8.	Purified water IP q.s.		
	kgs/Lts		
9.	140 mcl nasal pumps (Pfeiffer) code no. 44534		
10.	Nasal actuator code no. 47523		
11.	10 ml white opaque HDPE vial (Supplied by Kalmanns)		

Material to be taken on 100 % assay on as such basis.

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** Source: Daito



Material to be taken on 100 % assay on as such basis.