

2006	12	30
2007	03	02
2008	03	19
2008	05	20
2009	07	07
2011	05	25
2011	11	05
2016	04	26
2018	02	08
2018	06	22
2018	12	25
2020	06	30
2021	08	30

Budesonide Nasal Spray

Budinaide Bipenwuji

16 α , 17 α -22R, S-	-	-1, 4-	-11 β , 21-	-3, 20
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$$\text{C}_{25}\text{H}_{34}\text{O}_6$$

430.5

	N=171 %	N=615 %	N=1292 %	N=1172 %
	1.2	0.2	0.2	0.1
	7.0	1.5	1.5	2.2
	1.2	4.9	2.3	2.0
	4.7	5.2	9.0	3.7
	6.4	2.0	2.2	1.3
	0	0	0	0.1
	0.6	0.5	0.4	0.2

6 12

1%

	64mcg	128mcg	256mcg	
	N=32 %	N=102 %	N=36 %	N=106 %
	0	0	5.6	0
	0	2.0	2.8	0.9
	0	2.0	0	0
	3.1	2.0	0	1.9
	0	2.0	2.8	0
	6.3	2.9	2.8	0
	0	2.9	0	0.9
	0	2.9	0	1.9
	3.1	2.0	5.6	1.9
	0	3.9	0	1.9
	6.3	3.9	8.3	3.8
	0	5.9	0	4.7
	0	6.9	8.3	4.7
	3.1	4.9	2.8	5.7

	9.4	2.0	5.6	0.9
	0	1.0	5.6	1.9

5%

≥1/100 <1/10 ≥1/1,000

<1/100 ≥1/10,000 <1/1,000 <1/10,000

I IV

/

- -

- -

CYP3A4

P450

CYP3A4

8

8

5

PK

6

200mg

3mg

6

12

3

CYP3A4

1.

15

ACTH

32µg/ 64µg/

2.

SD

33%

256µg

0.64nmol/L 0.7

AUC

2. 7nmol·h/L

5.5nmol·h/L

3L/kg 85-90%
90% 6β- 16α-
1%

CYP3A4

0.9-1.4L/min

2-3

30

120 / 1 / 2 /

24

JX20170302

32ug/

H20171310

H20171309

J20180024

64ug/

H20171312

H20171311

J20180023

McNeil Sweden AB

Box 4007 SE-169 04 Solna

AstraZeneca AB
SE-151 85 Sodertalje,

219

200245
800-820-1188
400-888-3060

5-10

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|----|---|---|
| 1. | | |
| 2 | 1 | |
| 3. | | 2 |
| 4. | | |