

2007 02 08
2008 04 10
2010 09 26
2011 03 16
2012 02 13
2015 10 20
2016 03 04
2017 01 18
2017 04 26
2018 04 28
2018 11 30
2019 03 08
2019 04 08
2020 05 15
2020 10 12

2

6-17

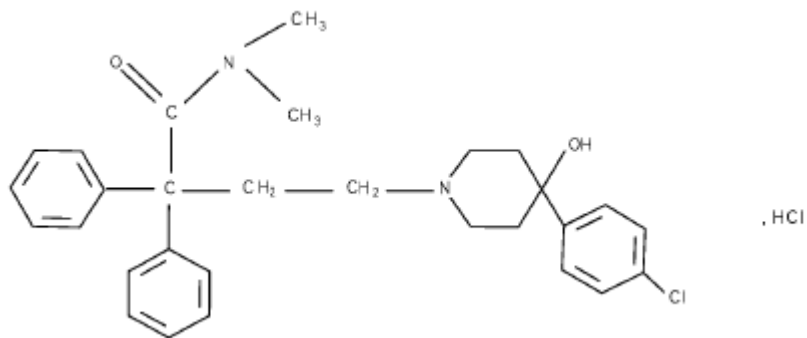
2

®

Loperamide Hydrochloride Capsules

Yansuan Luopaiding'an Jiaonang

N, N- -α, α- -4-()-4- -1-



$C_{29}H_{33}ClN_2O_2 \cdot HCl$

513.51

2 mg

6-17

—	2	1	1
—	2	1	
1~2	1~6		
—	8		3 /20
	8		

12

2755 (12) 26 ()
) 1%

1

1. 26 1%

	%
	(N=2755)
	1.2
	2.7
	1.7
	1.1

(N=2755) 1% 2

2. 26 1%

321 5 ()

1 52

3. 5 1%

	%
	(N=321)
	1.2
	2.8
	2.2
	1.2

(N=321) 1% 4

4. 5 1%

12

607 (10 13) 13
 () 1%

5

5. 12 13 1%

	%
	(N=607)
	1.2

12 (N=607) 1%

6

6.

12

13

1%

7

1/10

1/100, 1/10

1/ 1,000, 1/100

1/10,000, 1/1,000

1/10,000

7

7:

()

	()
	() (^a)
	(Stevens-Johnson)

a:

2

- .
- .
- .
- .

2~6

48

2

6

P-

16mg

P-

2~3

P-

(4mg) (CYP3A4 P-)

3~4 CYP2C8

2

4

13

(16mg) (CYP3A4 P-)

5

3

()

()

40 mg 792 mg

QT QRS /

/

Brugada

ECG QT

(1-3)

48

Ames

SOS

2.5 10 40mg/kg/ 20mg/kg/

11

10mg/kg/ 5

40mg/kg/ 21

10mg/kg/ 5

2.5 10 40mg/kg/

5 5 20 40mg/kg/

43

40mg/kg/

18 40mg/kg/

16mg / 21

μ-

0.3% ()

() 95%

P-

N-

CYP3A4

CYP2C8

11 9-14

6 / / 2 6 / / 20 / /

36

2020

H10910085

19

710304

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