

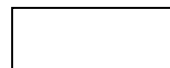
2006 10 26

2013 3 1

2015 6 8

2015 11 30

2017 8 16



60

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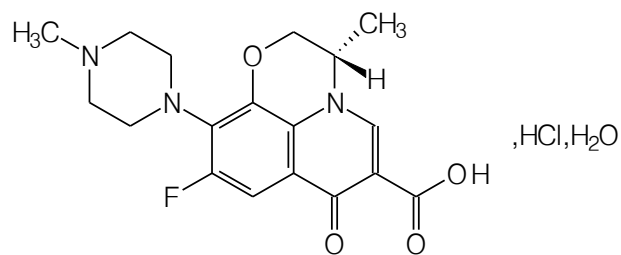
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Levofloxacin Hydrochloride Tablets

Yansuan Zuoyangfushaxing Pian

()- S -3- -9- -2 3- -10-(4- -1-)-7- -7H-
[1, 2, 3-*de*]-[1 4] -6-



C₁₈H₂₀FN₃O₄ · HCl · H₂O

415.85

1.

-

2.

7 14

MDRSP*]

[

MDRSP

MIC 2 µg/mL

/

5

3.

5

10 14

4.

5.

6.

È ('í ÈÀ'¼r¶

7.

10

9.

5

10

10.

11.

28

C₁₈H₂₀FN₃O₄ 0.1g

1.

1

250 mg 500 mg 750 mg 24

1

250 mg 500 mg 90 24 60

24 750 mg

1

50 mL/min 50 mL/min

1 50 mL/min

	24	2
	750 mg	7 14
	500 mg	7 14
	750 mg	5
	750 mg	5
	500 mg	10 14
	500 mg	7
cSSSI	750 mg	7 14
uSSSI	500 mg	7-10
	500 mg	28
cUTI AP ⁵	750 mg	5
cUTI AP ⁶	250 mg	10
	250 mg	3
50 kg 6 50 kg 6 7 8	500 mg 2	60 ⁸ 60 ⁸

[MDRSP]

[MDRSP]

cUTI

cUTI

28

14

2

18

6

2

2

6

1				2	
3,4					
50 kg	6	500 mg	24	60	⁴
50 kg	6	8 mg/kg 250 mg	12	60	⁴

1.

QT

/

QT

/

/

/

2.

		29		7537			
	50	74%	65	50%	71%		17%
	750 mg		250 mg	500 mg	1	2	
3	14	10					
				750 mg		250 mg	
	500 mg	1	2	4.3%			
	250 mg	500 mg			3.8%	750 mg	
		5.4%	250 mg	500 mg			
			1.4%	0.6%	0.4%	0.3%	6i6đ
	0.2%	750 mg					

/

5 6 1%
 0.1 1%
 3%

5		1%
/		% N=7537
		1
		4
		6
		3
		1
		7
		5
		3
		2
		2
		2
		2
		1
		1 ^b
		1
		1
		1

a. N = 7274
 b. N=3758

6	0.1	1%	N=7537
/			
			a
			a
			/

a. N = 7274

3.

7

7

/	
	/
	EEG
	QT
	Stevens-Johnson /

18

1.

2.

60

3.

4. QT

QT

QT

IA

QT

5.

/
/
/

6.

Stevens-Johnson

A B

CDAD

CDAD

10.

/

11.

/

/

12.

" V"

7,000

14

65

6

13.

6

14.

C

810 mg/kg/

9.4

160 mg/kg/

1.9
50 mg/kg/

810 mg/kg/

1.1

25 mg/kg/

0.5

18

14

6 16

mg/kg

1534 6 16

10 mg/kg 2 500 mg 5

1340 893

60 1

	N = 1340	N = 893 ^a	p ^b
60	28 2.1%	8 0.9%	p = 0.038
1 ^c	46 3.4%	16 1.8%	p = 0.025

a. /

b. Fisher's

c. 1199 804

1

1

8/46 17%

35/46 76%

7 9 80%

2

14 65 74 1,945 864 12 26 75 65 1081

65

QT QT IA
QT

1.

2.

R- S- AUC

3.

INR

4.

CNS

5.

14

AUC

6.

AUC

C_{max} k_e T_{max} $t_{1/2}$

7.

AUC

8.

AUC $t_{1/2}$ 27% 38 30 CL/F CL_R 21% 35

9.

1500 mg/kg

250 mg/kg

GOT/GPT/ALP
/

1

2

3

1.

(

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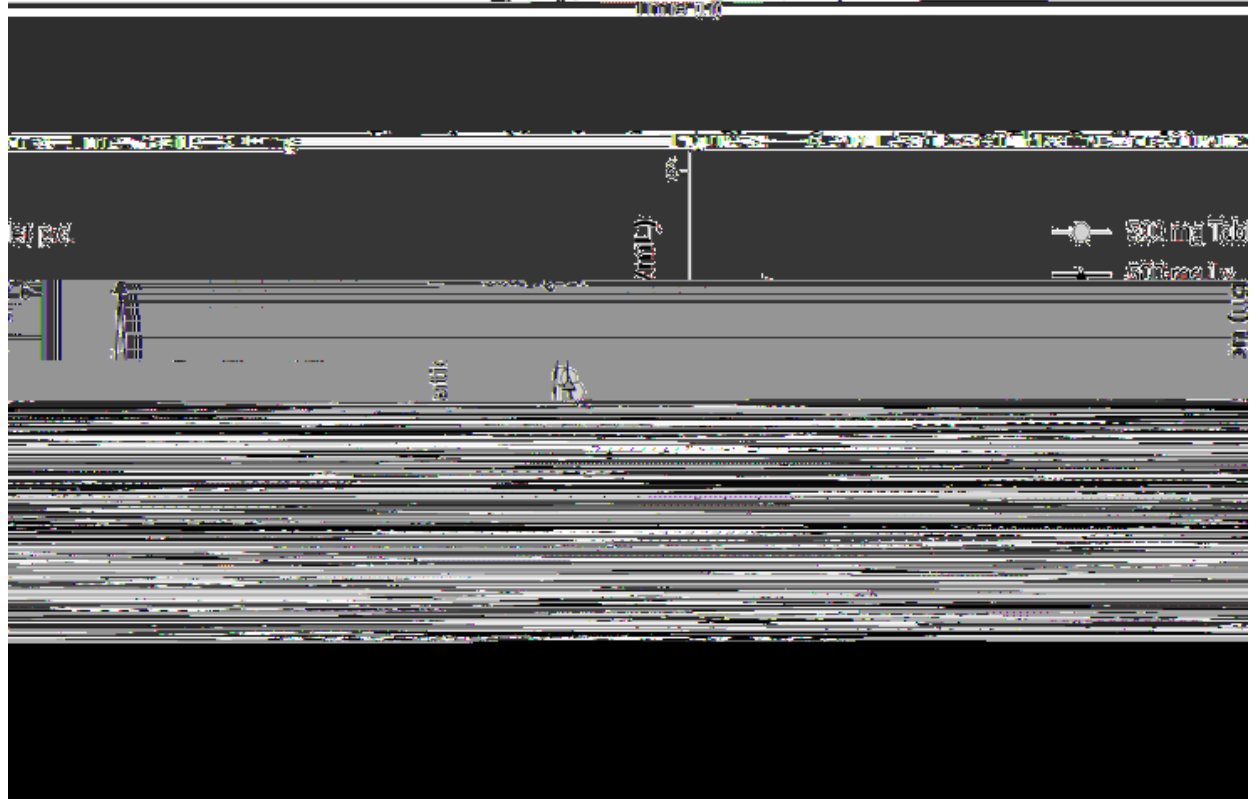
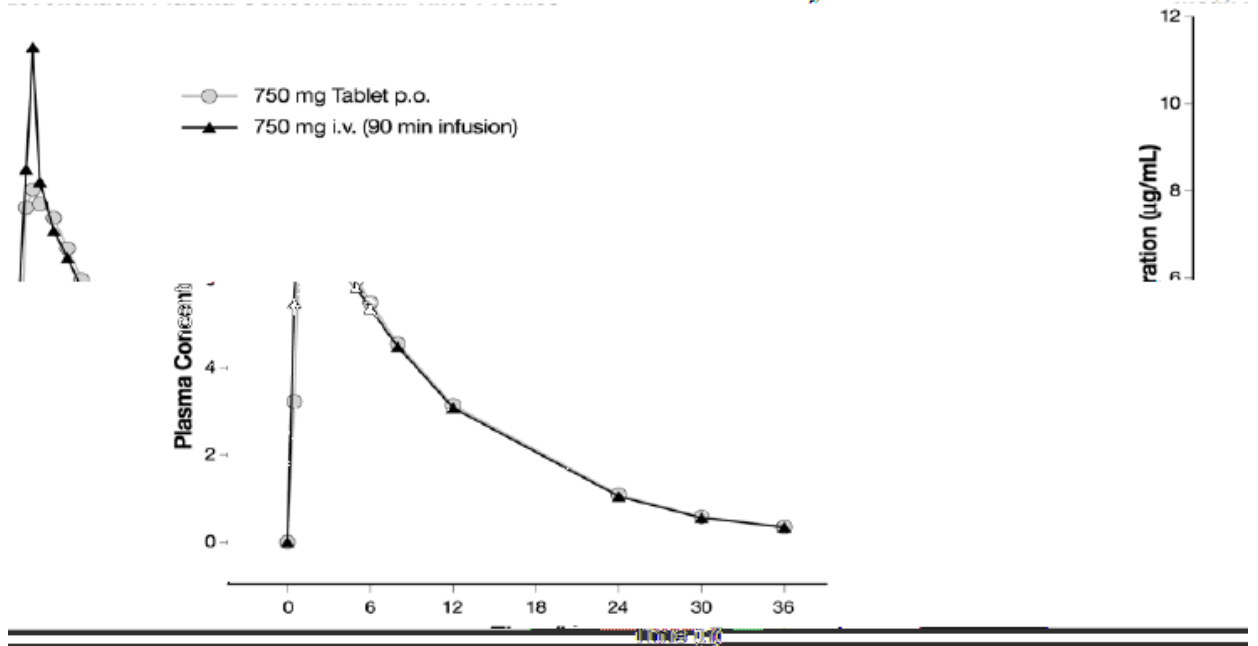
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500 mg p.o.							
500 mg p.o.							

/
 /
 250 mg 18 53 500 mg 60 750 mg 90
 18 54 48h 500 mg CL_{CR} 20 50
 mL/min 500 mg
 22 75
 18 80
 18 36
 66 80
 19 55
 500 mg F 0.99 ± 0.08 750 mg F=0.99 ± 0.06
 ND =
 500 mg 750 mg 1 2
 99
 500 mg 60
 750 mg 90
 Mean ± SD 6.2 ± 1.0 µg/mL
 Mean ± SD 11.5 ± 4.0 µg/mL
 500 mg 500 mg 750 mg 48
 Mean ± SD 5.7 ± 1.4
 0.5 ± 0.2 µg/mL 1

Figure 1: Mean Plasma Concentration (µg/mL) versus Time (h) for 750 mg p.o. and 750 mg i.v. (90 min infusion).



L

			500 mg	750 mg		74	112
						3	
				750 mg	500 mg		AUC
	2	AUC		1			
		500 mg	24			2	5
2.4	11.3	µg/g					
							/
	1	10 µg/mL		24%	38		

96 142mL/min
N- 4 72 87 5 D- 48
6 8 144 226 mL/min
24 35
7.6 66 80 6 500 mg
6 16 7mg/kg
17 8mg/kg 12 1 250mg 6 AUC₀₋₂₄
C_{max} 500mg 24 1
7.5 6.1 500 mg
72 48 24
50 mL/min
CAPD CAPD

6 1 12 1
10 2

24

2015
H20057797



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