

警示语：死亡率增加；QT 间期延长

死亡率增加

在一项安慰剂对照试验中，观察到本品治疗组的死亡风险（9/79，11.4%）较安慰剂治疗组（2/81，2.5%）增加。仅在不能另外提供有效的治疗方案时，才服用本品。

QT 间期延长

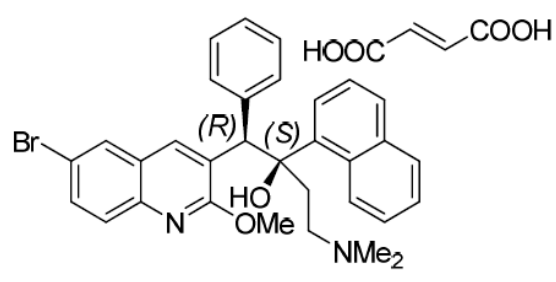
服用本品可能出现 QT 延长。同时服用可延长 QT 间期的药物可能引起叠加的 QT 延长作用。监测心电图。出现明显的室性心律失常或者 QTcF 间期 $>500\text{ms}$ 时，应停用本品。

®

Bedaquiline Fumarate Tablets

Fumasuan Beidakuilin Pian

1R 2S -1- 6- -2- -3- -4- -2- 1-
 -1- -2- 1:1



671.58 (555.50 + 116.07)

20

≥18

MDR-TB

DOT

II

MDR-TB

•

NTM

- HIV

100 mg $C_{32}H_{31}BrN_2O_2$

DOT

3 MDR-TB

4

MDR-TB

400mg

1

2

200mg

3

48

22

24

24

24

1 2

3

200mg

3

B Child-Pugh B

$\leq 0.001\%$

QT

335

8

2 24

1 3

1 2

MDR-TB

4

MDR-TB

3

MDR-TB

1 35.0% 17.5% 12.5% 9.4% 25.6%

8 10.1% 16 19.8%

HIV 7 8.9% 6 7.4%

1

1 1

	N=79	N=81
	n (%)	n (%)
	30 (38)	26 (32)
	26 (33)	18 (22)
	22 (28)	10 (12)
	14 (18)	9 (11)
	9 (11)	6 (7)
	7 (9)	3 (4)
*	7 (9)	1 (1)
	6 (8)	3 (4)
	2 (3)	1 (1)
* AST ALT		

3

1

2

3

11/102[10.8%] 6/105[5.7%]

3

22/230[9.6%]

3

5

1						120		
[9/79	11.4%	2/81	2.5%	p =0.03	95%		[1.1%	18.2%]]
9		5			2			
24		1		8				
329								

HIV

3	6.9%	16/233
9		1

C208 C209

24

1

WHO

MDR-TB

2

120

9/79 11.4%

2/81 2.5%

24

1

HIV

QT

QT

• QT

•

• QT

•

•

•

•

QT

○

○ QTcF >500ms ECG

ECG

QT

4

ALT AST

• 2

• 8

• 5 2

5

CYP3A4 /

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

14

6

/

/

1 2

3

200mg

3

7

8

B

AUC 2

1 2 AUC
6 12

/

65

1 CYP3A4 /

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

CYP3A4

14

2

MDR-TB

3

/

HIV MDR-TB

400mg /

100mg

/

CYP3A

4 QT

QTc

QT

QT

3

24

17

QTcF

31.9ms

24

12.3ms

QTc

QTcF

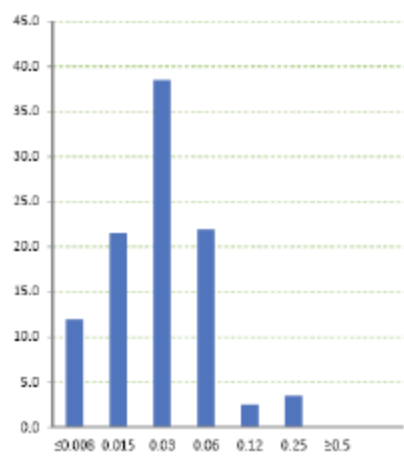
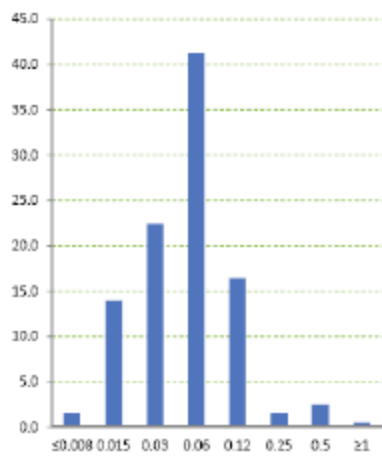
500ms

ECG QT

1		5						
		/			MDR-TB	18	24	
		12				24		
2	400mg	1	22	200mg	3			
	79				81			
120								
					66			
			63%		34	35%	15%	HIV
	CD4	468	/µL				62%	18%
		25						
		24						
		83		125	2	24	120	
2	1	24	120	MDR-TB				

	24 + N = 67	24 + N = 66	[95%CI] P-
24			
	78%	58%	20.0% [4.5%, 35.6%] 0.014
*	22%	42%	
	1%	0%	
	21%	35%	
	0%	8%	
120 **			
	61%	44%	17.3%[0.5%, 34.0%] 0.046
*	39%	56%	
	12%	3%	
	16%	35%	
	10%	18%	
* ** 24 96			

2 1
8 24 MDR-TB []
] n=23 MDR-TB n=24
21
23 MDR-TB
8 8 24
38.9% 95%CI [12.3% 63.1%] p 0.004 15.7% 95%CI
[-11.9% 41.9%] p 0.32
3 2b 233 6 MDR-TB
TB MDR-TB
24 24
NTP 120
120 1



1

N- M2 M2 23% 31%
4 6 M2
M2 QT

AUC [700mg 5 C_{max}
1.75] C_{max}
22 g 558
2

99.9% 164L

CYP3A4 N- M2
CYP M2 4 6
C_{max} N- M2
5.5
M2

2

0.001%

400mg M2 AUC_{672h} 8 Child Pugh B 20%

≤0.001%

200mg 3 MDR-TB

MDR-TB

MDR-TB

AUC 34%

24

HIV-TB

65

MDR-TB

3

-

CYP2C8/9/10 CYP2C19 CYP2D6 CYP2E1 CYP3A4 CYP3A4/5 CYP4A CYP450 CYP1A2 CYP2A6 CYP1A2 CYP2C9 CYP2C19 CYP3A4

CYP3A4

					400mg	1	14					
	400mg	1	4					AUC _{24h}	C _{max}	C _{min}		
	22% [90% CI	12	32]	9% [90% CI	-2	21]	33% [90% CI	24	43]
									300mg			
	600mg	1	21					AUC		52% [90%		
	CI -57	-46]									
						400mg	1			/		
					300mg/2000mg		1					
	AUC											
					MDR-TB							
						400mg				400mg	/	
	100mg	2				24						

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JX20180268

H20171366

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