

/QUVIVIQ
Daridorexant Hydrochloride Tablets
Yansuan Dalileisheng Pian

(S)-(2-(5- -4- -1H- [d] -2-)-2- -1-)(5- -2-(2H-1,2,3- -2-)

)

C₂₃H₂₃ClN₆O₂·HCl
487.38

K30

25mg " 25 "
50mg " 50 " Idorsia " "
Idorsia " "

/

C₂₃H₂₃ClN₆O₂ 1 25mg 2 50mg

25mg 50mg 30

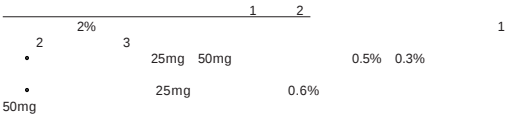
7

CYP3A4 CYP3A4
CYP3A4 CYP3A4
CYP3A4 CYP3A4 25mg
CYP3A4 CYP3A4 ® NS
Child-Pugh 7-9 25mg
Child-Pugh ≥ 10

3 2 3 [1 2] 1 9 [3]
10mg 1 50mg 25mg 1847 40% 2 25mg 10mg
50mg N 308 25mg N 618 10mg 12 N 306 N=615 576
6
1 1 2% 5%

	25 mg N 310 %	50 mg N 308 %	N 309 %
*	6	7	5
*	6	5	4
*	2	3	2
*	0	3	2

*

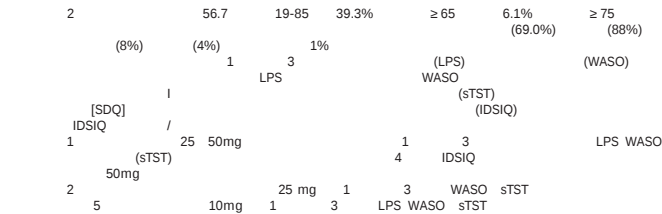
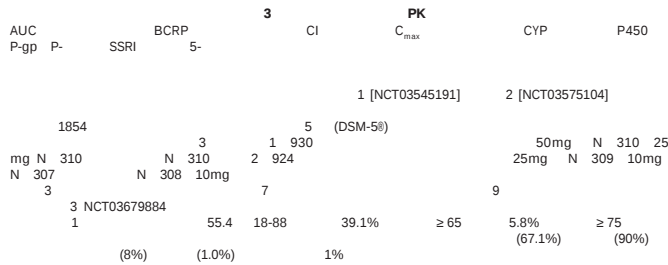
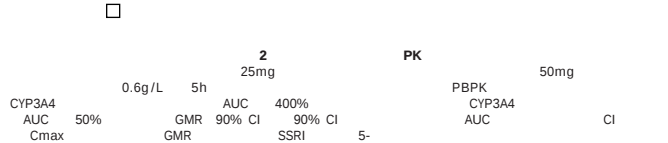


[

1
CNS CNS
50mg
CNS CNS
CNS CNS

2 / Ć C S

CYP3A4	
	CYP3A4
	CYP3A4 25 mg
	CYP3A4
CYP3A4	
	CYP3A4
	CYP3A4
	/



/ N		1			3		
	(SD)	(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)	LSM (95% CL)
WASO	min	PSG					
50 mg (310)							
LPS	min	PSG					
50 mg (310)							
25 mg (310)							
(310)	67 (40)	46 (36)	-20 [-23, -129]				
STST	min						
50 mg (310)	313 (58)	358 (74)	44 [38, 49]	22* [14, 30]	372 (79)	58 [51, 64]	20* [11, 29]
25 mg (310)	310 (60)	345 (66)	34 [29, 40]	13* [5, 20]	358 (72)	48 [41, 48]	10* [1, 19]
(310)	316 (53)	338 (65)	22 [16, 27]		354 (73)	38 [31, 44]	
IDS IQ							
50mg 310	22.5 (7.2)	18.6 (7.8)	-3.8 [-4.3, -3.2]	-1.8 * [-2.5, -1.0]	16.5 (8.1)	-5.7 [-6.4, -5.0]	-1.9 * [-2.9, -0.9]
25mg 310	22.1 (6.9)	19.4 (7.1)	-2.8 [-3.3, -2.2]	-0.8 [-1.5, 0.0]	17.3 (7.6)	-4.8 [-5.5, -4.1]	-1.0 [-2.0, 0.0]
310	22.3 (6.9)	20.3 (6.9)	-2.0 [-2.6, -1.5]		18.5 (7.8)	-3.8 [-4.5, -3.1]	

* CL WASO LPS LSM IDS IQ= PSG SD sTST

5 1 3

2

I N			1		3		
	(SD)	(SD)	LSM (95% CL)	LSM (95% CL)	(SD)	LSM (95% CL)	LSM (95% CL)
WASO	min		PSG				
25 mg (309)	106 (49)	80 (44)	-24 [-28, -20]	-12* [-18, -6]	80 (49)	-24 [-29, -19]	-10* [-17, -4]
(308)	108 (49)	93 (50)	-13 [-17, -8]		91 (47)	-14 [-19, -9]	
LPS	min		PSG				
25 mg (309)	69 (41)	42 (39)	-26 [-31, -22]	-6 [-12, -1]	39 (37)	-29 [-33, -24]	-9 [-15, -3]
(308)	72 (46)	50 (40)	-20 [-24, -16]		49 (46)	-20 [-24, -15]	
stST	min						
25 mg (309)	308 (53)	353 (67)	44 [38, 49]	16* [8, 24]	365 (70)	56 [50, 63]	19* [10, 28]
(308)	308 (52)	336 (63)	28 [22, 33]		347 (65)	37 [31, 43]	
IDSiQ							
25 mg (309)	22.2 (6.2)	18.7 (6.5)	-3.5 [-4.1, -2.9]	-0.8 [-1.6, 0.1]	17.0 (7.0)	-5.3 [-6.0, -4.6]	-1.3 [-2.2, -0.3]
(308)	22.6 (5.8)	19.8 (6.3)	-2.8 [-3.3, -2.2]		18.4 (6.6)	-4.0 [-4.7, -3.3]	

4 sTST 1