e k N

核准日期:2022年03月01日
修改日期:2022年11月01日

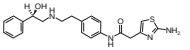
®

说明书

Mipabegpm l Ssqrai l ed-peleaqe Tablerq
Milabeilm l g Hsa l qhinia l

2-(2- -1, 3- -4-)-N-[4-(2-y[(2R)-2- -2-] {)]

$C_{23}H_{37}N_4O_3S$
396.51



OAB / k
50 k g

50 k g k k k

GFR < 15 k l/ k i l /1.73 k ² Child-Psgh C
P4503A CYP3A

		CYP3A ³	
¹		50 k g	25 k g
		50 k g	25 k g
		25 k g	
²		50 k g	25 k g
		25 k g	

1. GFR 60 | 89 k l/ k i l /1.73 k ² GFR 30 | 59 k l/ k i l /1.73 k ² GFR 15 | 29 k l/ k i l /1.73 k ² k
2. Child-Psgh A Child-Psgh B k
3. CYP3A

k

18 k k

. / 8433 OAB 5648
622 1 365 k k
12 88% 4%
k 50 k g 2.9%
1.2% 0.1% k 0.2% k
1 12
k

12 k
≥ 1/10 ≥ 1/100 <1/10) ≥ 1/1,000 <1/100 ≥ 1/10,000 <1/1,000
<1/10,000 k k

1

MedDRA					
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	* *				

*

k ≥ 180 k k Hg / ≥ 110 k k Hg
k

GFR<15 k l/ k i l /1.73 k ²
k GFR 15 | 29 k l/ k i l /1.73 k ² β γ
25 k g k GFR 15 | 29 k l/ k i l /1.73 k ² CYP3A
β γ k

Child-Psgh C k
Child-Psgh B CYP3A β γ k
k ≥ 160
k k Hg ≥ 100 k k Hg k
QT
QT β γ k
QT QT k
k
OAB
BOO OAB k
k OAB k
/ k
k k k
k

CYP2D6
CYP2D6 CYP2D6
CYP2D6 k

C
k
k
MRHD 22 14 k
/ 7 17
0 ⅓0 ⅓0 ⅓100 300 k g/kg k AUC MRHD 50 k g AUC 0 ⅓ ⅓6 ⅓22 96 k
MRHD 50 k g 6 / k MRHD
22 k k
/ 6 20
0 ⅓3 ⅓0 30 k g/kg k AUC MRHD 50 k g AUC 0 ⅓1 ⅓4 36 k
MRHD 14 /
NOAEL MRHD k MRHD 36
17 1 k
7 20 0 ⅓0 ⅓0 100 k g/kg/
k AUC MRHD 0 ⅓ ⅓6 22 k MRHD
6 21 k MRHD 22
4 92.7% 98.8% 21
k k 30 k g/kg MRHD 22 4
7 5% | 13% k MRHD 22
k

k k 2 k
k k
k
18 k k
≥ 65 $C_{k,av}$ -
AUC 18-45 k k

k CYP3A4 ⁽CYP2D6 ⁾ ⁾
UGT P- P-gn OCT OCT1 ⁽OCT2 OCT3 k
CYP CYP2D6 CYP3A k
P-gn k

CYP2D6
CYP2D6 β γ k CYP2D6
k CYP2D6 CYP2D6
k
k 100 k g k
IR 160 k g k
CYP2D6 CYP
CYP k
CYP3A/P-gn AUC 1.8 k CYP3A / P-gn
k GFR30 | 89 k l/ k i l /1.73 k ² Child-Psgh A
CYP3A 25 k g k β γ
k GFR15 | 29 k l/ k i l /1.73 k ² Child-Psgh B CYP3A
β γ β γ k
CYP3A P-gn k CYP3A P-gn
k
CYP2D6
CYP2D6 15 CYP2D6 k IR
$C_{k,av}$ AUC 79% $C_{k,av}$ AUC 90% 229% k
241% k
CYP2D6 ⁽1C
k CYP2D6
k
P-gn k P-gn $C_{k,av}$ AUC 29% 27% k
k
k P-gn P-gn k
k k k
k
400 k g k 1 /6
100 / bn k 3 /6 k 300 k g 10 k
k k
k

12 / /
k 59 18-95 72% 28% ⁽48%
52% k 495
k
3 1 24 2
24 k
2 3 k
2:

	046,047,074	
		50 k g
24 FAS-I		
l	878	862
	2.73	2.71
'	-1.10	-1.49
' 95%CI	--	-0.40 (-0.58, -0.21)
n	--	<0.001#
24 FAS		
l	1328	1324
	11.58	11.70
'	-1.20	-1.75
' 95%CI	--	-0.55 (-0.75, -0.36)
n	--	<0.001#
k l FAS		
l	1328	1322
	159.2	159.0
'	9.4	21.4
' 95%CI	--	11.9 (8.3, 15.5)
n	--	<0.001#
FAS		
l	1325	1323
	2.39	2.42
'	-0.15	-0.26
' 95%CI	--	-0.11 (-0.16, -0.07)
n	--	<0.001#
24 FAS-I		
l	858	834
	2.42	2.42
'	-0.98	-1.38
' 95%CI	--	-0.40 (-0.57, -0.23)
n	--	<0.001#
24 3 4 FAS		
l	1324	1320
	5.61	5.80
'	-1.29	-1.93
' 95%CI	--	-0.64 (-0.89, -0.39)
n	--	<0.001#