

2016 11 23

2019 04 11

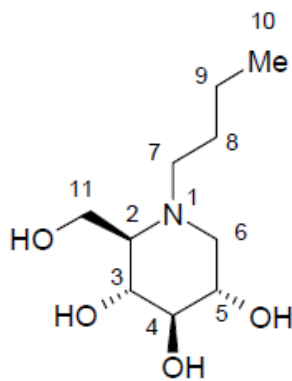
2020 06 19

® Zavesca®

Miglustat Capsules

Maigesita Jiaonang

(2R,3R,4R,5S)-1- -2- -3,4,5-



$C_{10}H_{21}NO_4$

219.28

C

0.1g

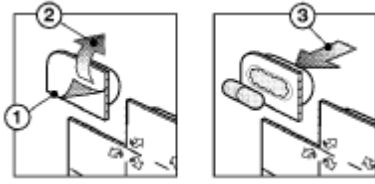
C

12

0.2g

12

(m ²)	
>1.25	0.2g
>0.88- 1.25	0.2g
>0.73- 0.88	0.1g
>0.47- 0.	



- 1.
- 2.
- 3.

11
50 - 200mg

247
2.1 132 1

40 C

			>1%				
		≥ 1/10	≥ 1/100	< 1/10		≥1/1000	<1/100
≥ 1/10000	< 1/1000		<1/10000				

/

55%

6 12

/

1

37% 1

58% C

1-3

80%

-

/

< 30 ml/min/1.73 m²

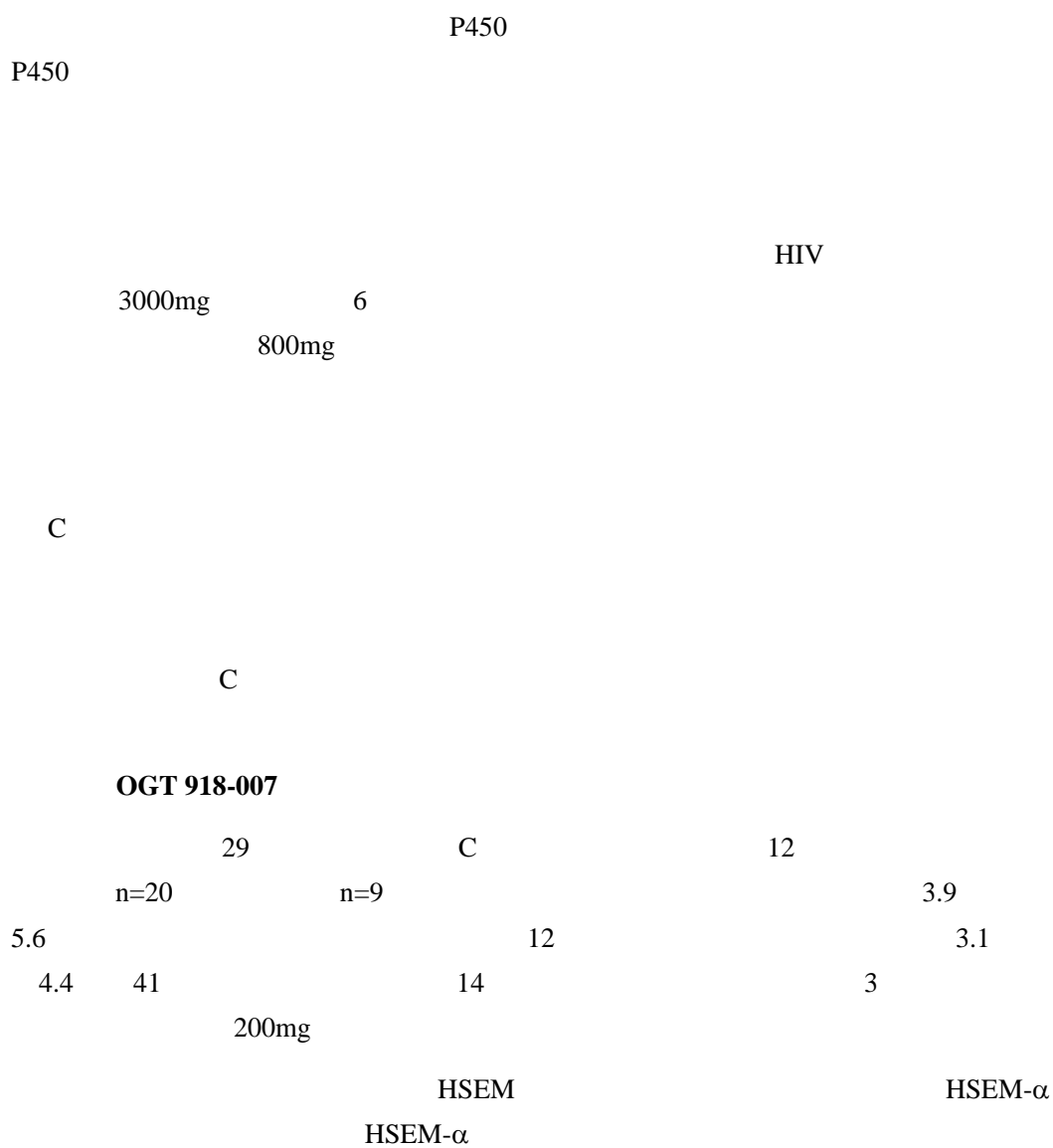
C

6 C
1

C
40 - 50%

C

/



1 OGT 918-007 12 HSEM-α

		(95% CI) /		(95% CI)	(95% CI)
		(n=8)	n=18		(n=10)
HSEM-α	^a	-0.050 (-0.608, 0.509)	-0.376 (-0.746, -0.005)	-0.326 (-1.000, 0.348)	-0.465 (-0.752, -0.178)

ANCOVA)				p = 0.327	
HSEM-α	a	0.055 (-0.443, 0.553)	-0.463 (-0.796, -0.129)	-0.518 (-1.125, 0.089) p = 0.091	
ANCOVA)					

a
HSEM =

12

CI =

1.22 p = 0.17] 12 80% / 0.4 [95% CI 0.13 24

12 SAI / SAI
0.087 [95% CI -0.287 0.461] 0.802
[95% CI 0.220 1.385] ANCOVA -0.715 [95%
CI -1.438 0.007 p = 0.052] /

/ Folstein MMSE
12
1.219 [95% CI -0.060 2.498] -0.352 [95% CI -2.213 1.510]
ANCOVA -1.571 [95% CI -0.692 3.834 p = 0.165]

C

Stage I Survey

66 C
1.5 3.1
1 43
/ / C

6 C
1

C

C

4		180	840	4200mg/kg/		>180mg/kg/
		6				
52		180	420	840	1680mg/kg/	>180mg/kg/
AUC		4				
2		85	165	495	825mg/kg/	>495mg/kg/
		50				
4		35	70	105	140mg/kg/	105 mg/kg/
		10				
52		750		2000mg/kg/		>750 mg/kg/ AUC
		4				
2		85	165	495	825mg/kg/	≥85mg/kg/
				26		300 600 1200mg/kg/
1200 mg/kg/	AUC				7	
	52			750	2000mg/kg/	≥750 mg/kg/
AUC				6		
	Ames					
					14	
20	60	180mg/kg/	20mg/kg/			
		14			20 mg/kg/	mg/m ²
6				60mg/kg/		
2						

60 180mg/kg/ 14 17 20
 ≥ 2
 6 ~18 15 30 45mg/kg/ 15mg/kg
 20 60 180mg/kg/ 6 20
 ≥ 2
 >20mg/kg/

CD-1 104 210 420 500mg/kg/
 3 6 7

CD-1

SD 100 30 60 180 mg/kg/
 1 2 5

:

C 3 1 HIV

2
 C_{max} 36% t_{max} 2
 AUC 14%

83L

(CL/F) 230 ± 39ml/ 70% - 80%
 100mg ¹⁴C 6 - 7 83% 12%
 5% 150

1

C

—

3 - 15 3

5-16 C

200mg

C_{max} AUC_τ

100mg

1

2

6 3

31.4% -67.2%

—

CL/F

CL/F

40% 60%

18 - 29 ml/min

CL/F

70%

—

BMI

—

> 70

30°C

84 /

60

JX20130040

H20160635

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