



托泽®

# 瑞舒伐他汀依折麦布片(I) 说明书

请仔细阅读说明书并在医师指导下使用药品

Rosuvastatin Calcium and Ezetimibe Tablets (I)  
瑞舒伐他汀依折麦布片(I)

10mg C<sub>22</sub>H<sub>29</sub>FN<sub>3</sub>O<sub>6</sub>S 10mg

依折麦布  
C<sub>22</sub>H<sub>29</sub>FN<sub>3</sub>O<sub>6</sub>S  
1001.13

瑞舒伐他汀  
C<sub>28</sub>H<sub>37</sub>F<sub>2</sub>NO<sub>3</sub>  
409.4

LDL-C

HoFH

LDL

Child-Pugh

112  
185

2,396

10mg

11,308

4%

1/1000 <1/100 1/10000 <1/1000 1/10 <1/10000 1/100 <1/10

MedDRA	1/1000 <1/100	1/10000 <1/1000	1/10 <1/10000	1/100 <1/10
		2		
		5		
			2	
				5
		1,2		
		3		
		2,5		
		2,4 2,5		
		4,5		
		2	2	
		2	2	5 5
		3 3		
		3		
		2	2,5	
		2 2 2,3 3 3	3 3	
		3	3 3 3 4 4	
		2		
		2 5 5		
		2		
		2 2,5		
		5 5 5		
		2,4 2,4 2,4		
		-	2 5	
				DRESS ?
		2,4,5		
		3 3 3 4 4,5 4		
		2,5 2,5		
		2		
		2	2	
		2 5 /	5	
		2		
		2		
		ALT / AST 4		
		ALT / AST 3 CPK 3 -	3 3	
		2 3		
		3 3 4 4		
		2 5		

1 5.6mmol/L BM>30kg/m<sup>2</sup> -

2 /

3 N=2396 N=11308 N=1159

4 N=9361

5

CK >5x ULN CK >20mg

ALT / AST 3x ULN 0.5% 0.3% 0.4%

1 0.1% 929 0.4% 4 1,674 917 4 0.2% 1 0.1% 786

>10x ULN 52 18

3x ULN 1.1% 1 CPK 10x ULN 0% 10 17 n=248 ALT / AST 3% 4 ALT /

AST 3x ULN CPK 2% 2 10x ULN / 0% n=138

1A2 2D6 2C8 2C9 3A4 N- P450 P450 CYP2A6 CYP3A4 P450 P450 P450

3 ULN

50% 2

AUC 55% K 12

LDL-C 10mg

CPK 5mg (CK)

>5x ULN (>5x ULN) 5 7

HMG-CoA /

HMG-CoA >70

>5x ULN

5x ULN HMG-CoA (>5x ULN)

(IMNM)( ) IMNM

HMG-CoA ( )

HMG-CoA ( )

ULN 3 3x 3

HMG-CoA 40mg ( )

3- -3- A(3-hydroxy-3-methyl glutaryl coenzyme A, HMG-CoA) (Glycated haemoglobin A1C, HbA1c) ( 5.6 6.9mmol/L BM >30kg/m<sup>2</sup>)

( )

- SJS DRESS

( HIV )

INR 7

5mg 18

<1mmol 23mg

HMG-CoA

>70 5mg

18

AUC 7 1

8 >50mL/min 10mg AUC 12

3.4 2.3-7.9 (n=17) 8 20

mg +51% 12 2 7 100mg 100mg AUC 15% -10%

1.5 1.7

C<sub>max</sub> AUC 2

1g/ HMG-CoA

1 300mg 3 7 /100mg 10mg AUC C<sub>max</sub> 1

BCRP OATP1B1 /

P450 P450 P450 P450 P450

50% 2

AUC 55% K 12

LDL-C 10mg

