

2023 01 19

2023 01 31

Vinorelbine Tartrate Soft Capsules

Jiushisuan Changchunruibin Ruanjiaonang

3',4'- -4'- -8'-

$C_{45}H_{54}N_4O_8 \cdot 2 C_4H_6O_6$

1079.12

20mg C<sub>45</sub>H<sub>54</sub>N<sub>4</sub>O<sub>8</sub>

•

60mg/m<sup>2</sup>

3

80mg/m<sup>2</sup>

60mg/m<sup>2</sup>

500/mm<sup>3</sup>

500~1000/mm<sup>3</sup>

60mg/m<sup>2</sup>

|                       |       |                 |           |       |      |
|-----------------------|-------|-----------------|-----------|-------|------|
| 60mg/m <sup>2</sup> / | >1000 | ≥500<br><1000 1 | ≥500<br>2 | <1000 | <500 |
| mg/m <sup>2</sup> /   | 80    | 80              | 60        |       | 60   |

80mg/m<sup>2</sup>

500/mm<sup>3</sup>

500~1000/mm<sup>3</sup>

80mg/m<sup>2</sup>/

60mg/m<sup>2</sup>/

|                       |       |                 |                 |      |
|-----------------------|-------|-----------------|-----------------|------|
| 80mg/m <sup>2</sup> / | >1000 | ≥500<br><1000 1 | ≥500<br><1000 2 | <500 |
| mg/m <sup>2</sup> /   |       | 80              | 60              |      |

60mg/m<sup>2</sup>/

500/mm<sup>3</sup>

500~1000/mm<sup>3</sup>

60mg/m<sup>2</sup>/

80mg/m<sup>2</sup>/

•

80mg/m<sup>2</sup>

30mg/m<sup>2</sup> 60mg/m<sup>2</sup>

25mg/m<sup>2</sup>

132

B~

60mg/m<sup>2</sup>

1

8

80mg/m<sup>2</sup>

1

3

2

60mg/m<sup>2</sup>

80mg/m<sup>2</sup>

133

60mg/m<sup>2</sup>

1

8

75mg/m<sup>2</sup>

1

3

2

60mg/m<sup>2</sup>

80mg/m<sup>2</sup>

≥ 2m<sup>2</sup>

60mg/m<sup>2</sup>

120mg

80mg/m<sup>2</sup>

160mg

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<

1.5

ALT / AST

1.5

2.5

60mg/m<sup>2</sup>/

1.5 3

ALT AST

50mg/m<sup>2</sup>/

—————

316 132

184

60mg/m<sup>2</sup>/

80mg/m<sup>2</sup>/

MedDRA



G4

38°C

2.8 %

G3-4

• \_\_\_\_\_

SIADH

• \_\_\_\_\_

G1-2: 34.5%; G3-4: 4.1%.

• \_\_\_\_\_

G1-2:2.8%

• \_\_\_\_\_

G1-2:11.1%

G1-4:9.2% ; G3-4:1.3%

G1-4:4.1% G3-4:0.6%

G1-4:6% G3-4:0.6%

G1-2:3.8%

3

0.3%

• \_\_\_\_\_

G1-2:1.3%

• \_\_\_\_\_

• \_\_\_\_\_

G1-4 2.5% G3-4 0.3%;

G1-4 2.2% G3-4 0.6%

• \_\_\_\_\_

G1-4 2.8% G3-4 0.3%

G1-2 2.8%

• \_\_\_\_\_

G1-4

G1-2 3.8%

• \_\_\_\_\_

G1-4 25% G3-4 0.3%

G1-2 1.3%

3/4

< 1500/mm<sup>3</sup>

2

< 100000/mm<sup>3</sup>

\_\_\_\_\_

/

100mg

- 1500/mm<sup>3</sup> / 100000/mm<sup>3</sup>
- 80mg/m<sup>2</sup> 60mg/m<sup>2</sup> 80mg/m<sup>2</sup> 500/mm<sup>3</sup> 500 1000 /mm<sup>3</sup>  
60mg/m<sup>2</sup> 60mg/m<sup>2</sup>  
80mg/m<sup>2</sup>  
80mg/m<sup>2</sup>  
60mg/m<sup>2</sup>  
80mg/m<sup>2</sup>

CYP3A4

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- 
-

- $<$
- 1.5 ALT / AST 1.5 2.5 60mg/m<sup>2</sup>
- 1.5 3 ALT AST 50mg/m<sup>2</sup>

INR

• \_\_\_\_\_

• \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

• \_\_\_\_\_

• \_\_\_\_\_

• \_\_\_\_\_

C

•

P-



Ames

TK Locus

1/3      1      4.2mg/m<sup>2</sup>      1      9mg/m<sup>2</sup>      0.14

2      2.1mg/m<sup>2</sup>      7.2mg/m<sup>2</sup>

0.07    0.24      13      26

/

9mg/m<sup>2</sup>

0.33

6      1      5.5mg/m<sup>2</sup>

0.18

fetal

• \_\_\_\_\_

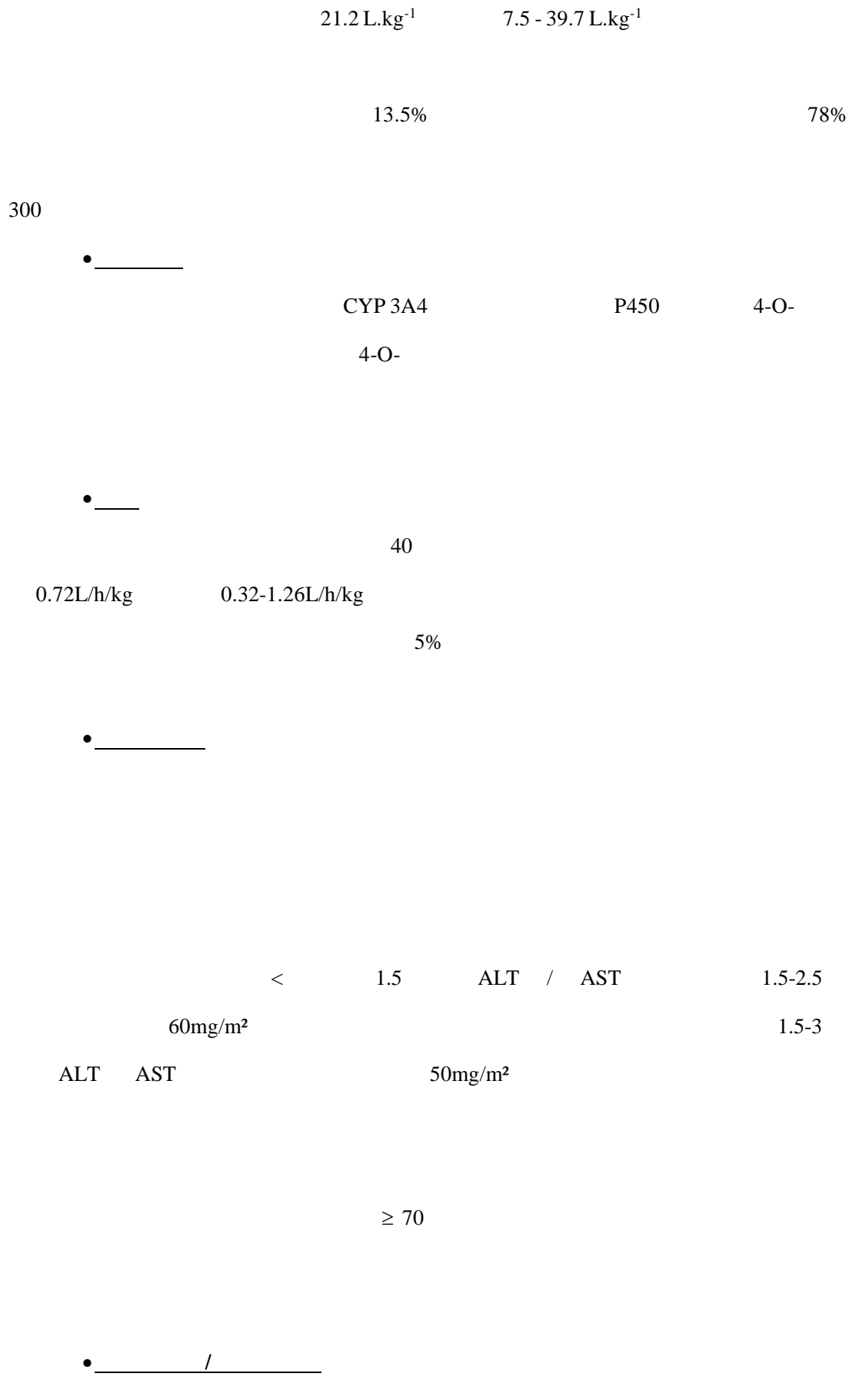
(C<sub>max</sub>)      130ng/ml      T<sub>max</sub>    1.5-3      80mg/m<sup>2</sup>

40%

60    80mg/m<sup>2</sup>      25

30mg/m<sup>2</sup>

100mg/m<sup>2</sup>      40%



PMNs

2 8

Σ Σ1 1 1 8

24

YBH15722022

H20233075