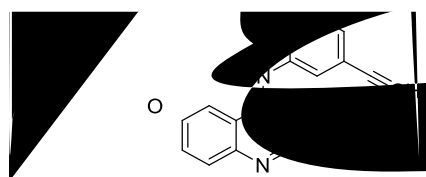


Erlotinib Hydrochloride Tablets

Yansuan Eluotini Pian



EGFR NSCLC 150mg/ 1 2

ILD

-

50mg

CYP3A4

CYP3A4

450mg

/

1 ENSURE

ALT

AST

2 (>2.5 5.0 ULN) ALT

2% 1% 3 (>5.0 20.0 ULN) ALT 1% 0%

2 (>1.5-3.0 ULN) 3 (>3.0-10.0 ULN)

4% <1%

<1%

/

	+ 1000 mg/m ² IV N=259			+ 1000 mg/m ² IV N=256		
	NCI CTC			NCI CTC		
	2	3	4	2	3	4
	17%	10%	<1%	11%	10%	3%

ALT	31%	13%	<1%	22%	9%	0%
AST	24%	10%	<1%	19%	9%	0%

NSCLC

EGFR

/

/

Child-Pugh B

15	10	30	1	
1		8	10	8
	> 3 ULN		> 3 ULN	
		> ULN	Child-Pugh A, B	C

18

NSCLC

NSCLC	66%	65	34%
65 65	0.78		

&

EGFR / I HER1
EGFR EGFR
EGFR /
19 21 L858R EGFR
EGFR EGFR
ATP EGFR

ALT AST

UV

Ames

150mg/d AUC

3

/

/

150mg/d

10

2

60mg/kg/d

10mg/kg/d

5mg/kg/d

CYP3A4

3

1 100mg 10 / 1 / 1 /
2 150mg 10 / 1 / 1 / 10 / 1 / 2 /

36

YBH12342020

/

- | | | |
|---|-------|-----------|
| 1 | 100mg | H20213411 |
| 2 | 150mg | H20213412 |