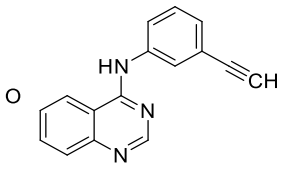
Erlotinib Hydrochloride Tablets

Yansuan Eluotini Pian



NSCLC

EGFR

150mg/ 1 2

ILD

-

/

50mg

CYP3A4

CYP3A4

CYP1A2

CYP3A4

450mg

/

St. Johnôs Wort

Child-Pugh 7-9

>

3 × ULN

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%

	150mg N=485			N=242		
	NCI-CTC			NCI-CTC		
	%	3 %	4 %	%	3 %	4 %
*	75	8	<1	17	0	0
	55	6	<1	18	<1	0
	52	8	1	38	5	<1
	52	14	4	45	16	4
	41	17	11	35	15	11
	33	3	0	24	2	0
	24	4	0	15	2	0
	17	<1	0	3	0	0
	13	<1	0	5	0	0
	12	0	0	4	0	0
	12	<1	0	2	<1	0
	12	0	0	3	0	0

	39	2	0	29	<1	0
*	39	13	3	30	9	2
	36	3	0	30	4	0
	22	<1	0	12	0	0
	19	2	0	14	<1	0
	16	0	0	11	0	0
	15	<1	0	10	0	0

	+ **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%

ÙU

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NSCLC EGFR

0.7% 0% /

5 9 39

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/

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 0.7

C h

AUO Ո- ﷺ ŧ k

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ɋ % ئ i

/

EGFR / I HER1

EGFR EGFR

EGFR /

19 21 L858R EGFR

EGFR EGFR

EGFR EGFR

ATP

EGFR

ALT AST

UV

Ames

150mg/d AUC

3 /

60mg/kg/d

150mg/d 10 10mg/kg/d

2 5mg/kg/d

291 NSCLC

204

AAG

Child-Pugh *7-9*

/

CYP3A4 3

1 100mg 10 / ×1 / ×1 /

2 150mg 10 / ×1 / ×1 / 10 / ×1 / ×2 /

36

YBH12342020

1	100mg	H20213411
2	150mg	H20213412