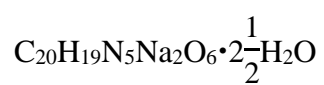
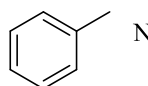


2007	01	24
2009	12	31
2011	06	26
2012	07	02
2014	11	19
2017	10	13
2020	09	10
2021	01	19
2022	06	28

Pemetrexed Disodium for Injection

Zhusheyong Peimeiqusai 'erna

N-{4-[2-(2-4,7-4-1H-[2,3-d]-5-)] }-L-



516.41

ALK

ALK

EGFR

EGFR

NSCLC

4

0.2g

"

"

500mg/m²

BSA

10

21

1

500mg/m² BSA 10 21

1

500mg/m² BSA 10 21

1 75mg/m² BSA 2

21 1 30 /

500mg/m² BSA

10 21 1

350~1000μg 7 5

21

B₁₂ 1000μg 3

B₁₂

4mg

WCC

ANC 1500 /mm³ 100,000 /mm³

45mL/min 1.5 AP

AST SGOT ALT SGPT 3

AST ALT 5

1-3

1-3

1

50,000/mm ³	<500/mm ³	75%
<50,000/mm ³		75%
<50,000/mm ³	^a	50%

^a NCI CTCAE CTCAE v2.0 NCI 1998 CTCAE 2 CTCAE=

3

2

2

a,b

		mg/m²	mg/m²
3	4	75%	75%
	3 4	75%	75%
3	4	50%	100%

^a NCI CTCAE

1.

2.

20%

20%

/

NSCLC

KEYNOTE-189

JMDB

è

4 JMDB

a

+ (N=839)

GGT

—

—

JMEN 4

NSCLC 2:1

21 500mg/m²

B₁₂

JMEN ECOG PS 2

45mL/min

B₁₂

JMEN 438 61

26-83 73% 65% 31% 2.9%

<2% 39% ECOG PS 0 5

96% 48% 6 21

23% 10 21

5 JMEN 438 5%

5 JMEN

a	(N=438)		(N=218)	
	(%)	3-4 (%)	(%)	3-4 (%)
	66	16	37	4
	15	3	6	1
	6	3	0	0
ALT	10	0	4	0
AST	8	0	4	0
	25	5	11	1
	19	1	6	1
	19	2	5	0
	9	0	1	0

/	7	1	2	0
	5	1	3	0
	5	2	2	0

PARAMOUNT 333 61

32 83 58% 94% 4.8% <1%

36% ECOG PS 0 4

3.3% 0.6% 22%

16%

6 PARAMOUNT 333 5%

6 PARAMOUNT

a	(N=333)		(N=167)	
	(%)	3-4 (%)	(%)	3-4 (%)
	53	17	34	4.8
	15	4.8	4.8	0.6
	9	3.9	0.6	0
	18	4.5	11	0.6
	12	0.3	2.4	0
	6	0	1.8	0
/	5	0.3	2.4	0
	5	0	3.6	0

^a NCI CTCAE 3.0

13% vs. 4.8% 1.5% vs. 0.6%

12% vs. 7% 6% vs. 0%

3 4

1% <5%

/ —

—

<1%

—

—

—
—
—
—

JMEI 1:1

21 1

500mg/m² 75mg/m²

B₁₂

JMEI ECOG PS 3

45mL/min

B₁₂

JMEI 265 58

22 87 73% 70% 24% 2.6%

1.8% <2% 19% ECOG PS 0

7 JMEI 265 5%

JMEI 7

7 JMEI

	16	2	12	1
/	15	1	17	1
	13	0	24	3
	6	0	4	0
	34	5	36	5
	8	0	8	0
/				
/	14	0	6	0
	7	0	2	0
	6	1	38	2

^a NCI CTCAE 2.0

1% 5%

— /

/ —

—

1%

JMCH

1:1

21

1

500mg/m²

75mg/m²

21

1

75mg/m²

226

1

222

1

226

74% n=168

B₁₂

14% n=32

12% n=26

JMCH

KPS

70

45mL/min

B₁₂

168

60

19

85

82%

92%

5%

3.0%

<1%

54%

KPS

90-100

/

6 / 2
93%

8 JMCH 5%
JMCH 8

8 JMCH / a

b	+ (N=168)		(N=163)	
	(%)	3-4 (%)	(%)	3-4 (%)
	56	23	13	3
	53	15	17	1
	26	4	10	0
	23	5	9	0
	11	1	10	1
	16	1	18	2
	5	0	1	0
	82	12	77	6
	57	11	50	4
/	23	3	6	0
	20	1	14	1
	17	4	8	0
	12	1	7	1
	5	1	1	0
	48	10	42	9
	7	4	1	1
	10	0	10	1
	8	0	6	0
/				
	16	1	5	0
	11	0	6	0

a JMCH 226 1 B₁₂ 222 1 168
8 163 ADR

b NCI CTCAE 2.0

1% 5%

—

/

—

—

— AST

ALT

GGT

—

1%

—

—

Stevens-Johnson

ORIENT-11

20%

10

JMID

106

102

2%

CTCAE 3

4

10 JMID

CTCAE 3 4

	(N=106) n (%)	(N=102) n (%)	P ^a
	22(20.8)	41 (40.2)	0.003
	7 (6.6%)	3 (2.9%)	0.333
	4 (3.8%)	21 (20.6%)	<0.001
/	5 (4.7%)	29 (28.4%)	<0.001
	7 (6.6%)	0 (0.0%)	0.014
	0 (0.0%)	5 (4.9%)	0.027
	3 (2.8%)	5 (4.9%)	0.492
	2 (1.9%)	4 (3.9%)	0.439

^a P Fisher N= n= CTCAE= 3 4

JMIL

252 AC 125

GC 127 AC

6 AC AC 3 4

GC 63 [50.4%] vs. 84 [66.1%] p=0.015 AC

43.2% 1 3 4 GC

55.9% p=0.045 AC 50 [40.0%] vs. 76 [59.8%] p=0.002

50 [40.0%] vs. 76 [59.8%] p=0.002 4 [3.2%] vs. 15 [11.8%]

p=0.015 GC

11 JMEN

5% CTCAE

11 JMEN 5%

a	b	(N=62)		(N=37)	
		(%)	3 4 (%)	(%)	3 4 (%)
		32.3	1.6	16.2	2.7
		30.6	1.6	13.5	0.0
	ALT SGPT	22.6	1.6	16.2	0.0
	/	17.7	0.0	5.4	0.0
	AST SGOT	16.1	0.0	16.2	0.0
		16.1	0.0	2.7	0.0
		14.5	0.0	2.7	0.0
	/	11.3	1.6	0.0	0.0
	-	11.3	0.0	0.0	0.0
		9.7	0.0	0.0	0.0
		8.1	0.0	0.0	0.0
	-	6.5	0.0	0.0	0.0
		6.5	0.0	0.0	0.0

ALT= AGC= ANC= AST=

CTCAE= CTCAE 3.0 NCI2003 G= N=

SGOT= SGPT= WBC=

a = 10% = 5% <10%

5%

b CTCAE 3.0 NCI2003

_____ B₁₂

 _____ B₁₂ 3/4 3/4

 _____ ANC 1500 /mm³
 100,000 /mm³
 ANC

 _____ <45mL/min
 <45mL/min

 _____ -
 - 45 79mL/min 2
 2 NSAIDs 1.3g/

5

2

NSAIDs

—

6

—

31

2

/

0.2g

21.5mg

65

65

65

65

(NSAIDs)

80 mL/min

NSAIDs

1600 mg/

1.3 g/

80

mL/min

NSAIDs

45-79 mL/min

2

2

NSAIDs

NSAIDs

NSAIDs

5

2

NSAIDs

NSAIDs

P450

CYP3A CYP2D6 CYP2C9 CYP1A2

INR

/

DHFR

GARFT

TS

TS GARFT

Ames

0.1 mg/kg/

0.006

9

500mg/m² 0.03

500mg/m² 0.0012

426

0.2-

838 mg/m²

10

9 L/m²

81%

24

70%-90%

OAT3

3

90 mL/min)

91.8 mL/min

3.5

19.3%

AUC

26 80

B₁₂

22 4 18 12 13 9
400 2480 mg/m² AUC
Cmax 2.30 L/h/m²
2.3

1 /

36

YBH13932020

H20051288

5

222069

4008285227

9:00-17:00

<http://www.hansoh.cn>

80395B07