

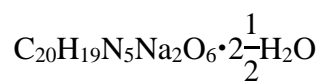
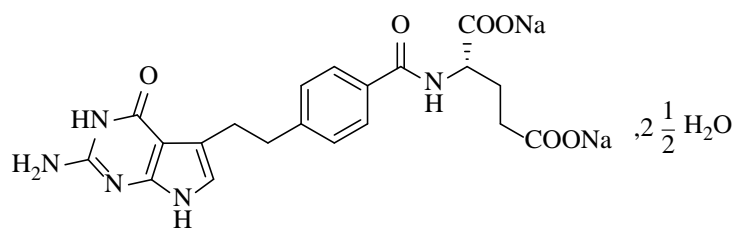
2020 12 01

2021 09 18

Pemetrexed Disodium for Injection

Zhusheyong Peimeiqusai erna

N-{4-[2-(2-amino-4,7-dihydro-1H-imidazo[2,3-d]pyridin-5-yl)ethyl]phenyl}acetamide disodium salt dihydrate



516.41

ALK

EGFR

ALK

EGFR
NSCLC

4

0.1g $C_{20}H_{21}N_5O_6$

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 /

10 21 1 500mg/m² BSA

350~1000μg 7 5
21
B₁₂ 1000μg 3
B₁₂

4mg

WCC

$\geq 45 \text{ mL/min}$ $\text{ANC} \geq 1500 / \text{mm}^3$ $\geq 100,000 / \text{mm}^3$
 ≤ 1.5 AP
 AST SGOT ALT $\text{SGPT} \leq 3$
 AST $\text{ALT} \leq 5$

1-3

1-3

$50,000/\text{mm}^3$	$< 500/\text{mm}^3$	75%
	$< 50,000/\text{mm}^3$	75%
	$< 50,000/\text{mm}^3$ ^a	50%

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

3

2

a,b

3	4	75%
		75%

3 4 $\text{MO} \pm \bullet \text{L}'\text{S}'\text{I} , ' + \dots$ 3 4

^a NCI CTCAE CTCAE v2.0 NCI 1998

25mg/mL

pH 6.6-7.8

4.

9mg/mL 0.9%

100mL

10

5.

PVC

6.

7.

24

2°C-8°C

24

0.9%

≥20%

≥20%

/

KEYNOTE-189

JMDB NSCLC

1:1 21 1

500mg/m² 75mg/m² n=839 21

1 8 1250mg/m² 1

75mg/m² n=830 B₁₂

JMDB ECOG PS 2

45mL/min

B₁₂

JMDB 839

61 26-83 70% 78% 16% 2.9%

2.1% <1% 36% ECOG PS 0

5

4 JMDB 839 ≥5%

JMDB 4

≥5%

	(%)	(%)	(%)	(%)
	90	37	91	53
	33	6	46	10
	29	15	38	27
	18	5	21	8
	10	4	27	13
	10	1	7	1

	43	7	45	5
	56	7	53	4
	40	6	36	6
	27	2	24	1
	21	1	20	0
/	14	1	12	0
	12	1	13	2
/	5	0	6	0
	9	0	12	1
	8	0	9	0
	12	0	21	1
/	7	0	8	1

^aNCI CTCAE 2.0

1% 5%

—
—
— AST ALT

1%

—
—
— 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				

1% 5%

/ — /

—

—

—

—

1%

—

/ —

—

/

—

—

PARAMOUNT

4

NSCLC

2:1

21

1

500mg/m²

B₁₂

PARAMOUNT

ECOG PS 2

45mL/min

B₁₂

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%

≥5%

	%	%	(

PS 3

45mL/min

B₁₂

265

58

70%

24%

2.6%

2%

19%

ECOG PS

0

265

≥5%

7

≥5%

(N=265)			
%	%	%	%
19	4	22	4
12	4	34	27
11	5	45	40
8	2	1	0
8	2	1	0
7	1	1	0
31	3	17	2
	2	24	3
	2	12	1

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

≥5%

%

%

%

	56	23	13	3
	53	15	17	1
	26	4	10	0
	23	5	9	0

—

—

9 JMCH
CTCAE 3 4

NCI
B₁₂

	N=168(%)	N=32(%)
/	23	38
	5	9
	11	31
	1	9
3/4	0	6
	4	

ORIENT-11

$\geq 20\%$

10

JMID

106

5%

CTCAE

5%

		(%)	(%)	(%)	(%)
		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

$\geq 10\%$

$\geq 5\%$

<10%

5%

b

CTCAE

3.0

NCI2003

B₁₂

B₁₂

B₁₂

3/4

3/4

ANC ≥ 1500 /mm³
ANC $\geq 100,000$ /mm³

<45mL/min
<45mL/min

-
-
2
45 79mL/min
NSAIDs
5
NSAIDs
2
2
1.3g/

6

31

2

/

0.1g

0.47mmol 11mg

65

65

65

1600 mg/ ≥ 80 mL/min NSAIDs

mL/min ≥ 1.3 g/ NSAIDs

2 ≥ 80

2 NSAIDs $\geq 45-79$ mL/min 2

NSAIDs NSAIDs

2 NSAIDs NSAIDs 5

P450

CYP3A CYP2D6 CYP2C9 CYP1A2

INR

500mg/m² 0.03

500mg/m² 0.0012

838 mg/m²

10

426

9 L/m²

0.2-

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

C_{max}

2.30 L/h/m²

2.3

36

YBH12702021

H20205050

5

222069

4008285227

9:00-17:00

602146B01