核准日期：2023年02月14日

说明书

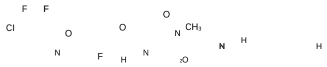
请仔细阅读说明书并在医师指导下使用

PRES

Regorafenib Tablets
Ruigefeini Pian

4-[4- {[4- -3-] } -3-]-N- -2- /

$C_{21}H_{15}ClF_4N_4O_3 \cdot H_2O$
500.83



*

1.
VEGF EGFR RAS mCRC
2.
GIST
3. HCC
40mg

160mg 4 40mg 21 28

30%

40mg
80mg 160mg
[HFSR/PPE] 1
1:

2
2:

Child-Pugh A Child-Pugh B
Child-Pugh C
M-2 M-5

4800
III 636 mCRC 132 GIST 374
HCC
≥ 30% /

2872
IIIb
* 3
MedDRA
≥ 1/10
≥ 1/100 <1/10 ≥ 1/1000 <1/100 ≥ 1/10000 <1/1000
3
MedDRA

MedDRA

*

*#

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**

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**MedDRA
DILI DILI
>20
ULN
1.5% <0.1%
18.2%
9.5% 1 2
15.2% 6.1% 0.7%

31.6%
17.2% 1 2 23.0%
5.7% 4.2% 3.3% 2.6%
1.0% 0.3%

CRC 51.4%vs.6.5% GIST 66.7%vs.15.2% HCC 51.6%vs.7.3%
1 2 CRC34.4% GIST44.7% HCC39.3% 3
17.1% CRC 22.0% GIST 12.3% HCC
CRC74.8% GIST88.2% HCC67.1% 3 20.5% CRC
23.5% GIST 13.5% HCC
CRC
29.6%vs.7.5% GIST 60.6%vs.25.8% HCC 31.0%vs.6.2%
1 2 CRC20.9% GIST31.8% HCC15.8% 3
8.7% CRC 28.0% GIST 15.2% HCC GIST 1 4
9.1%
1.9% 35.6% 54.5%
75 75 N 410 75
N 4108 13.7% 6.5%

4 4a
4 CRC CORRECT GIST GRID HCC RESORCE III

mCRC CORRECT GIST GRID HCC RESORCE

b b

a CTCAE 3.0 b CTCAE 4.0 *