



: 2007 01 16
: 2007 05 26
2008 04 18
2009 05 19
2009 12 02
2010 10 22
2011 01 10
2011 11 05
2012 02 27
2012 06 25
2012 08 28
2014 12 24
2015 02 09
2015 08 18
2015 12 14
2017 05 19
2017 07 17
2017 08 31
2018 02 01
2019 03 28
2019 07 24
2020 06 19
2021 04 08

警示语

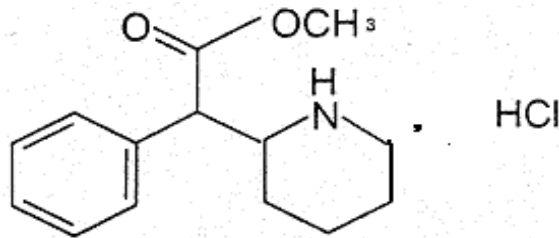
本品应慎用于有药物依赖史或酒精依赖史的患者。长期滥用会导致明显的耐药性和心理性依赖，并伴随不同程度的行为失常。尤其是在非肠道途径滥用药物时，可引起明显的精神病性发作。因对滥

用药物的停用可能引起严重的抑郁症，应对其停用过程进行监护。长期治疗停药时，可能会使一些潜在疾病症状显现，需要进行随访。

®

Methylphenidate Hydrochloride Prolonged-Release Tablets
Yansuan Paijiazhi Huanshipian

α- -2-



$C_{14}H_{19}NO_2 \cdot HCl$

269.77

18mg	2910	
K30		188
II		
36mg	2910	
K30		188
II		

DSM-IV

6-17

18-65

DSM-IV

ICD-10

/

1

18 36 mg

6

1

12

18 mg

18 36 mg

10-60 mg/

5 mg	2	3	18 mg
10 mg	2	3	36 mg
15 mg	2	3	54 mg
20 mg	2	3	72 mg

54 mg

72 mg

18 mg

1

108 mg

1%

ADR

4

639

ADHD

1

1%

ADR

1 4

1%

/	n=321 %	n=318 %
	2.8	2.2
*	2.8	0.3
	1.9	0
	1.9	0.9
	1.2	0.9
	6.2	3.8
	2.8	1.6
	2.2	0.9
* =0.6%		=2.2%

3

905

ADHD

2

1%

2 3

1%

/	n=596 %	n=309 %
	1.7	1.0
	1.3	1.0
	24.8	6.1
	4.2	1.3
	13.3	7.8
	8.4	2.9
	5.7	2.6
	4.4	2.6
	4.0	0
	3.2	0.6
	2.3	0.6
	1.5	0.6
	1.5	0.6
	1.3	0.6
*	1.5	0.6
	1.3	0.3
	1.3	0.3
	1.2	0.6
	1.0	0.3
	24.2	18.8
	7.4	5.5
	3.4	0.6
	1.2	0
	1.0	0.3
	1.3	0
	1.3	1.0
	2.0	0.3
	6.0	0
	4.5	0.6
	2.2	1.6
	1.3	0.6
	1.5	1.3
	1.2	1.0
	1.2	0.6
	15.1	3.6
	14.3	4.9
	2.0	1.9
	1.8	0.6

	1.5	0.6
	5.7	1.3
	1.3	0
	1.0	0.3
	1.0	0.3
	5.2	2.9
	4.7	4.2
	1.8	0.6
	1.2	0
	8.7	3.6
	3.0	1.9
	2.5	1.9
	1.0	0
*		

----- 1%

12 3782 ADHD

3 1% 1 2
3 12 1%

/	n=3782 %
	2.0
	1.1
	1.0
	2.4
	1.3
	1.2
	1.3
	1.4

----- 1%

4 1%

4

1%

/

5

t 1/10

t1/100 < 1/10

t1/1,000 < 1/100

t1/10,000 < 1/1,000

<1/10,000

5

5

NEC

*

14

ADHD

Tourette

Tourette

Tourette

Tourette

ADHD

/

0.1%

3482

4

0

ADHD

ADHD

14

7~10

36

10~13

7

3

2cm

2.7kg

/

/

2~4mm Hg 3~6bpm ,

3

2~6

1~4mm Hg

4~6bpm

-2~3bpm

-1~1mm Hg

0~1mm Hg

-1~1mm Hg

-2~0mm Hg

—

8
 n=40 108mg 60mg 5
 108mg []
 60mg -
 60mg
 n=49 54mg 108mg
 50mg 90mg
 54mg 108mg 50mg 90mg
 108mg
 50mg
 22%

—

—

—

—

5mg/kg

/

6

6

65

2

5-

/

—

4
ADHD
416 6~12
3 1 2
18 36 54 mg 12 3 15 30 45
mg 1 2 3 IOWA-Conners ADHD
/ 1

1 IOWA-Conners /
1 2 SKAMP Swanson Kotkin Agler M-Flynn
Pelham ADHD
12 2
SKAMP

1 =

2 SKAMP SEM 1 2

177 4

72 mg/ 1.4 mg/kg/ 13~18 ADHD

4 220 ADHD

177 72 mg/

n=87 n=90 ADHD 18~72 mg/

627 18~65

7 5 36~108 mg/ 5

6 18 36 72 mg/ 1

5 ADHD AISRS

36~108 mg/ 18~65 ADHD 7

226 110 116 36

mg/ 18 mg/

	36~108 mg/				AISRS		
	6						5
3		18	36	72 mg		18 mg	n=101
n=102	72 mg/		n=102		n=96	ADHD	36 mg
					CAARS	Conners	ADHD

Ames

		18		160mg/kg/			
				80	mg/kg	8	mg/m ²
		30mg/kg/					
15	mg/kg	3		mg/m ²	AUC		
PPAA							1~2
		200mg/kg/					100
	mg/kg	40		mg/m ²			
B6C3F1					60mg/kg/		
						30	mg/kg
	4	mg/m ²					

F344 45mg/kg/
 22 mg/kg 5 mg/m²
 p53+/- 24 60~74mg/kg/

1~2
 6~8
 3 1
 1 3

36 1 18mg 3 5mg

6 r

	18mg n=36	5mg n=35
C _{max} ng/mL	3.7 r 1.0	4.2 r 1.0
T _{max}	6.8 r 1.8	6.5 r 1.8
AUC _{inf}	41.8 r 13.9	38.0 r 11.0
t _{1/2}	3.5 r 0.4	3.0 r 0.5

1

AUC t_{1/2}

18 36 54mg C_{max} AUC_(0-inf)

C_{max} AUC_(0-inf)

1/40

54~144mg/ / MPH

D - PPAA C_{max} AUC_{inf}

4

54~144mg/ PPAA MPH

13 16 ADHD

18~72mg/ C_{max} AUC_{TAU}

3.5

PPAA

D -

3

90%

D -

80%

—

$AUC_{(0-inf)}$

36.7ng h/mL

37.1ng h/mL

—

$AUC_{(0-inf)}$

—

6

—

80%

PPAA

—

15 / /

24

JM20110003

18mg H20170262

36mg H20170263

18mg TPI20170701

36mg TPI20170702

18mg J20171049

36mg J20171050

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