



: 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

警示语

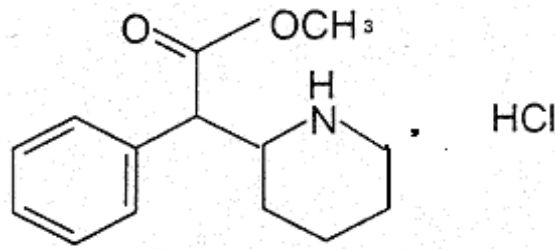
本品应慎用于有药物依赖史或酒精依赖史的患者。长期滥用会导致明显的耐药性和心理性依赖，并伴随不同程度的行为失常。尤其是在非肠道途径滥用药物时，可引起明显的精神病性发作。因对滥用药物的停用可能引起严重的抑郁症，应对其停用过程进行监护。长期治疗停药时，可能会使一些潜在疾病症状显现，需要进行随访。

®

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 6~12

DSM-IV

ICD-10

/

1 18 36 mg

6

1

12

18mg

54mg

1

1

1 18mg

5mg 2

20mg

5mg 3

18mg

10mg 2

40mg

10mg 3

36mg

54mg

54mg

— 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%

/	
NEC NEC	
*	

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

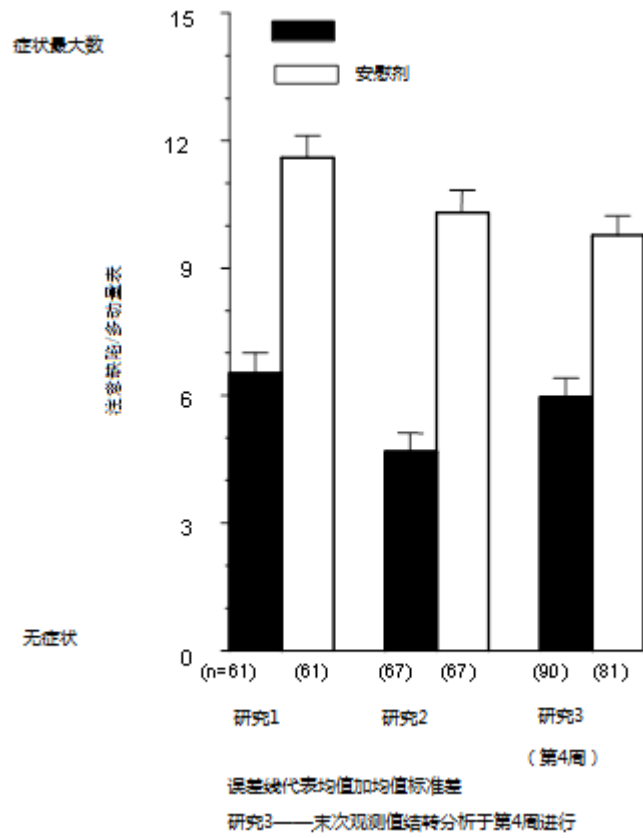
2

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

	2	SKAMP		SEM	1	2
						4
	177					
	72 mg/	1.4 mg/kg/		13~18	ADHD	
4			220	ADHD		
				177		72 mg/
						18~72 mg/
	n=87	n=90		ADHD		
				627	18~65	
7				5	36~108 mg/	5
			6	18	36	72 mg/
	5			ADHD		1
						AISRS
		36~108 mg/		ADHD		

	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

±

	18mg n=36	1	5mg n=35	3
ng/mL C _{max}	3.7 ± 1.0		4.2 ± 1.0	
T _{max}	6.8 ± 1.8		6.5 ± 1.8	
ng·h/mL AUC _{inf}	41.8 ± 13.9		38.0 ± 11.0	
t _{1/2}	3.5 ± 0.4		3.0 ± 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

α- - PPAA C_{max} AUC_{inf}

4

54~144mg/

PPAA

MPH

13 16

ADHD

18~72mg/

C_{max} AUC_{TAU}

3.5

PPAA

α - -

3

90%

α - -

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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