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# 口服Ⅰ型Ⅲ型脊髓灰质炎减毒活疫苗（人二倍体细胞） Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral

## 说明书

请仔细阅读说明书并在医师指导下使用

- 【药品名称】** 通用名称：口服Ⅰ型Ⅲ型脊髓灰质炎减毒活疫苗（人二倍体细胞）  
英文名称：Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral  
汉语拼音：Koufu I Xing III Xing Jisuihuizhiyan Jiandu Huoyimiao (Ren Erbeiti Xibao)
- 【成分和性状】** 本品系用Sabin株脊髓灰质炎减毒活疫苗Ⅰ、Ⅲ型减毒株分别接种于人二倍体细胞，经培养、收获病毒液、制成二价液体疫苗。为澄清无异物的橘红色液体。  
有效成分：Ⅰ、Ⅲ型Sabin株脊髓灰质炎减毒活病毒。  
辅料：氯化镁。
- 【接种对象】** 本疫苗用于2月龄及以上的婴幼儿。
- 【作用与用途】** 本疫苗服用后，可刺激机体产生抗Ⅰ型和Ⅲ型脊髓灰质炎病毒免疫力。用于预防脊髓灰质炎Ⅰ型和Ⅲ型病毒导致的脊髓灰质炎。
- 【规格】** 每瓶1.0ml（10人份）。每1次人用剂量为2滴（相当于0.1ml），含脊髓灰质炎活病毒总量应不低于6.12lgCCID<sub>50</sub>，其中Ⅰ型应不低于6.0lgCCID<sub>50</sub>，Ⅲ型应不低于5.5lgCCID<sub>50</sub>。
- 【免疫程序和剂量】** 本品（bOPV）按国家卫生计生行政主管部门制定的免疫策略使用。  
本品使用前应在室温下于10分钟内融化成液体；若发生变色禁止使用（详见【注意事项】）。  
**用法：**本品用于与脊髓灰质炎灭活疫苗（IPV）序贯接种。基于目前临床试验结果推荐序贯程序为3剂，间隔4~6周。  
本品不同序贯接种（口服1剂或2剂本疫苗）的免疫原性结果可参见【临床试验】。  
本品尚未进行加强免疫和免疫持久性研究。  
**用量：**本品每1次使用剂量为2滴（相当于0.1ml），须使用本品所附的专用无菌口服给药器（滴管）。
- 【不良反应】** **（1）本品境内临床试验：**  
在境内开展的1项注册临床试验中，共200名2月龄健康婴儿接种本疫苗，其中100名婴儿首剂接种IPV后口服两剂本疫苗；另外100名婴儿接种两剂IPV后口服一剂本疫苗。同时以3剂IPV和3剂IOPV为对照。系统的安全性观察自疫苗接种开始至全程接种后30天，长期安全性观察自全程接种后31天至6个月。  
针对本品境内临床试验报告的不良反映，按国际医学科学组织委员会（CIOMS）推荐不良反应发生率的分类：十分常见（≥10%）；常见（≥1%且<10%）；偶见（≥0.1%且<1%）；罕见（≥0.01%且<0.1%）；十分罕见（<0.01%），进行描述如下：  
**十分常见：**  
发热、腹泻  
**常见：**  
烦躁（易激惹）、呕吐  
本试验样本量有限，未观察到发生率为偶见及以下的不良反映。  
本品使用中若出现上述未提及的任何不良反映，请及时告知医师。

表1 受试者每剂接种后1个月内总体及常见不良反映发生情况

疫苗	不良反映总体发生率	发热	腹泻	烦躁（易激惹）	呕吐
bOPV	37.50%~43.62%	35.11%~39.36%	4.17%~10.64%	2.08%~4.26%	0.00%~3.19%
IOPV	37.62%~56.99%	32.67%~54.84%	4.04%~10.75%	1.03%~5.94%	0.00%~3.09%
wIPV	40.40%~56.00%	31.00%~41.30%	6.06%~15.00%	2.17%~13.00%	0.00%~7.00%

注：bOPV：本品，含Sabin株Ⅰ、Ⅲ型脊髓灰质炎减毒活病毒；  
IOPV：脊髓灰质炎减毒活疫苗糖丸（人二倍体细胞），含Sabin株Ⅰ、Ⅲ、Ⅱ型脊髓灰质炎减毒活病毒；  
wIPV：脊髓灰质炎灭活疫苗，含Salk株Ⅰ、Ⅱ、Ⅲ型脊髓灰质炎灭活病毒抗原。

### （2）本品上市后安全性监测

下述不良事件是基于本品上市后的自发报告。这些报告来自于样本量不确定的人群，故无法准确估计其发生率。  
皮肤及皮下组织类疾病：皮疹、荨麻疹、斑丘疹、麻疹样皮疹、猩红热样皮疹、过敏性紫癜、血管性水肿；  
感染及侵袭性疾病：疫苗接种后脊髓灰质炎、脑膜炎、脑炎；  
胃肠系统疾病：腹痛、胃肠道刺激、恶心；  
神经系统性疾病：惊厥或热性惊厥、急性弛缓性麻痹、周围性麻痹、婴儿痉挛、运动障碍、嗜睡；  
血管与淋巴管类疾病：血小板减少性紫癜、血小板减少症；  
免疫系统疾病：超敏反应、过敏性休克；  
各种肌肉骨骼及结缔组织疾病：肌肉抽搐；  
代谢及营养类疾病：食欲减退。

### （3）境外已上市同类疫苗

根据境外已上市同类疫苗相关文献报道，可能出现皮疹、寒战、无力（疲劳）、肌肉疼痛和关节痛；包括少见的感觉异常（刺痛感、四肢发麻）、局部麻痹（轻度瘫痪）、神经炎（神经性发冷）及脊髓炎，以及极罕见的口服后引起脊髓灰质炎疫苗相关病例（VAPP）。

### 【禁忌】 下列情况严禁使用本疫苗：

- (1) 已知对该疫苗的任何组分，包括辅料及硫酸庆大霉素过敏者。
- (2) 患急性疾病、严重慢性疾病、慢性疾病的急性发作期、发热者。
- (3) 免疫功能缺陷、免疫功能低下或正在接受免疫抑制治疗者。
- (4) 妊娠期妇女。
- (5) 患未控制的癫痫和其他进行性神经系统疾病者。

**【注意事项】**

- (1) 本品只供口服，严禁注射！
- (2) 有以下情况者慎用：家族和个人有惊厥史者、患慢性疾病者、有癫痫史者、过敏体质者。
- (3) 本品系活疫苗，如需要应使用37℃以下温水送服，切勿用热水送服。
- (4) 本品容器开启后，如未能立即用完，应置于2~8℃，并于当天内用完，剩余均应废弃。一旦本疫苗出现混浊、变色（紫色或黄色）、疫苗瓶有裂纹者均不可使用。
- (5) 应备有肾上腺素等药物，以备偶有发生严重过敏反应时急救用。接种者在接种后应在现场观察至少30分钟。
- (6) 避免反复冷冻融和严禁加热融化，以免影响免疫效果。
- (7) 注射免疫球蛋白者应至少间隔二个月以上再接种本疫苗，以免影响免疫效果。
- (8) 本品未开展与其他疫苗同时接种的相关研究。使用不同的减毒疫苗进行预防接种时，建议间隔至少一个月以上。
- (9) 本品上市后安全性监测发现，肛周脓肿接种本品后引起脊髓灰质炎疫苗相关病例（VAPP）风险较高，故肛周脓肿者慎用本品。

**【临床试验】**

本品（bOPV）境内注册临床试验采用随机、盲法、同类疫苗对照的非劣效设计，600名2月龄健康儿童随机分为wIPV-bOPV、bOPV、wIPV-tOPV-tOPV、wIPV-wIPV-bOPV、wIPV-wIPV-tOPV、wIPV-wIPV-wIPV、tOPV-tOPV-tOPV研究组，每组按序贯或全程免疫程序接种3剂，每剂间隔4~6周。共计200例按序贯程序接种本品。免疫原性评价采用细胞培养微量中和试验（细胞病变抑制法）检测免疫前、全程接种后30天血清脊髓灰质炎病毒I、II、III型抗体水平。易感人群接种后抗体 $\geq 1:8$ 、非易感人群接种后抗体滴度4倍及以上增长判定阳转。结果见下表：

表2 基础免疫后一个月时的血清抗体阳转（4倍增长）率（PPS）

		wIPV+2bOPV		wIPV+2tOPV		2wIPV+bOPV		2wIPV+tOPV		3剂 wIPV		3剂 tOPV	
		n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
易感人群	I型	40/40	100.00	55/55	100.00	41/41	100.00	41/41	100.00	39/39	100.00	37/37	100.00
	II型	47/61	77.05	60/60	100.00	63/63	100.00	56/56	100.00	54/54	100.00	41/41	100.00
	III型	77/78	98.72	70/72	97.22	68/68	100.00	76/76	100.00	68/68	100.00	67/67	100.00
非易感人群	I型	45/46	97.83	29/31	93.55	40/45	88.89	40/45	88.89	36/43	83.72	38/41	92.68
	II型	1/25	4.00	22/26	84.62	8/23	34.78	25/30	83.33	16/28	57.14	35/37	94.59
	III型	8/8	100.00	12/14	85.71	16/18	88.89	10/10	100.00	12/14	85.71	11/11	100.00
总人群	I型	85/86	98.84	84/86	97.67	81/86	94.19	81/86	94.19	75/82	91.46	75/78	96.15
	II型	48/86	55.81	82/86	95.35	71/86	82.56	81/86	94.19	70/82	85.37	76/78	97.44
	III型	85/86	98.84	82/86	95.35	84/86	97.67	86/86	100.00	80/82	97.56	78/78	100.00

注：bOPV：本品，含Sabin株 I、II型脊髓灰质炎减毒活病毒；  
tOPV：脊髓灰质炎减毒活疫苗九（人二倍体细胞），含Sabin株 I、II、III型脊髓灰质炎减毒活病毒；  
wIPV：脊髓灰质炎灭活疫苗，含Salk株 I、II、III型脊髓灰质炎灭活病毒抗原。

表3 受试者基础免疫后一个月时的血清抗体水平（PPS）

	I型		II型		III型	
	GMT(95%CI)	增长倍数	GMT(95%CI)	增长倍数	GMT(95%CI)	增长倍数
wIPV+2bOPV	1822.01 (1444.3~2298.5)	161.66	11.01 (8.97~13.51)	1.95	698.14 (565.37~862.09)	153.00
wIPV+2tOPV	1100.89 (875.6~1384.2)	133.04	279.19 (218.50~356.74)	41.94	480.91 (359.04~644.15)	98.68
2wIPV+bOPV	1167.98 (849.7~1605.5)	107.46	53.49 (43.82~65.29)	8.76	1068.89 (755.9~1511.4)	184.55
2wIPV+tOPV	864.44 (630.7~1184.9)	86.55	136.94 (480.02~914.79)	103.99	777.98 (575.7~1051.4)	160.38
3剂 wIPV	301.42 (246.33~368.85)	28.89	136.94 (106.68~175.77)	19.7	370.52 (293.54~467.68)	72.43
3剂 tOPV	1459.89 (1124.9~1894.6)	153.98	271.39 (216.87~339.62)	36.43	477.11 (382.39~595.31)	94.73

注：bOPV：本品，含Sabin株 I、II型脊髓灰质炎减毒活病毒；  
tOPV：脊髓灰质炎减毒活疫苗九（人二倍体细胞），含Sabin株 I、II、III型脊髓灰质炎减毒活病毒；  
wIPV：脊髓灰质炎灭活疫苗，含Salk株 I、II、III型脊髓灰质炎灭活病毒抗原。

以上试验获得的安全性数据请参见【不良反应】。

**【贮藏】** 于-20℃以下保存，运输过程可在冷藏条件下（ $\leq 8^{\circ}\text{C}$ ）进行。

**【包装】** 玻璃管制注射剂瓶，注射液用溴化丁基橡胶塞。3瓶/盒。  
本品另配接种本疫苗专用的无菌口腔给药器（滴管），无菌口腔给药器（滴管）另行包装。

**【有效期】** 自生产之日起，有效期为24个月。

**【执行标准】** YBS00282015 2025年版《中华人民共和国药典》

**【批准文号】** 国药准字S20150014



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## Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral

### DESCRIPTION

Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral (bOPV) is a vaccine containing suspensions of types I and III live attenuated polioviruses (Sabin strain). The product, which is prepared by inoculation of the type I and III attenuated polio virus strains into the human diploid cells and then the virus was incubated and harvested, is a reddish orange liquid. One Molar magnesium chloride (MgCl<sub>2</sub>) is added as a stabilizer.

The production process of bOPV complies with WHO's requirements.

### COMPOSITION

Each dose of 2 drops (0.1 ml) contains

Polio virus (Sabin)

Type I: Not less than 10<sup>6</sup> CCID<sub>50</sub>

Type III: Not less than 10<sup>6</sup> CCID<sub>50</sub>

Stabilizer: 1 M MgCl<sub>2</sub>

Residual Antibiotics: Gentamicin not more than 50 ng/dose

### INDICATIONS

Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral indicated for active immunization against type I and III polioviruses.

### ADMINISTRATION AND DOSAGE

bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multi-dose vial by dropper supplied with the vaccine. Care should be taken not to contaminate a multi-dose dropper with saliva.

The vaccines should be naturally thawed into liquid at room temperature for 10 minutes before use. Thawing with heat is strictly prohibited.

Once opened, multi-dose vials should be kept between +2 C and +8 C.

Multi-dose vials of bOPV from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO Policy Statement: Multi-dose Vial Policy (MDVP) Revision 2014 WHO/IVB/14.07).

- The vaccine is currently prequalified by WHO.
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
- The expiry date of the vaccine has not passed.
- The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer- recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

### IMMUNIZATION SCHEDULE

bOPV is indicated for routine and supplementary immunization activities (SIAs) against type I and III poliovirus in all age groups.

The advised vaccination schedule for each country must be in accordance with the national or WHO recommendations.

A clinical trial in China shows that seroconversion rates to type I and III poliovirus are higher than 94% with the vaccination schedule of IPV-bOPV-bOPV or IPV-IPV-bOPV at 4-6 week intervals.

bOPV can be given safely and effectively at the same time as the vaccines recommended by Expanded Programme on Immunization (EPI) if this fits into the vaccination schedule.

If bOPV cannot be given at the same time as live attenuated vaccines, an interval of at least one month should be left between both vaccinations.

### ADVERSE REACTIONS

Very common (may affect more than one in 10 people) adverse reactions: mild fever, diarrhea. Common adverse reactions (may affect less than one in 10 people but more than one in 100 people): irritability and vomiting. [The result above is based on a clinical trial in China.]

Generally, these will not require special treatment, but can be treated according to specific symptoms when needed.

Very rarely, there may be vaccine-associated paralysis (one case per 1 million doses administered). Persons in close contact with the vaccinees may very rarely be at risk of vaccine associated paralytic poliomyelitis.

### SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In case of diarrhea and/or vomiting, (as well as gastro-intestinal infection), the dose received will not be counted as part of the immunization schedule and should be repeated after recovery.

The attenuated poliomyelitis viruses multiply in the gut. The faecal excretion of the vaccine viruses may persist for several weeks and may also be transmitted to the contacts of the vaccinees; contacts of vaccinees should therefore be warned about the need for strict personal hygiene.

Immunosuppressive treatment may reduce the immune response, may favour the multiplication of the vaccine viruses and may increase the length of excretion of the vaccine viruses in the stools.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

### Pregnancy

Although there is no evidence that live attenuated polioviruses have an adverse effect on the foetus, in accordance with general principles, the vaccine should not be given to pregnant women unless they are exposed to a definite risk of infection with wild polioviruses. The risk/benefit of the use of the vaccine should be evaluated in comparison to the use of inactivated polio vaccines.

### CONTRAINDICATIONS

For those suffering from acute diseases, serious chronic diseases, acute attack of the chronic diseases, fever, uncontrolled epilepsy or other ongoing nervous system diseases or with a history of allergic reaction to any known components in the vaccine, including auxiliary materials and gentamicin sulphate, the vaccine is contraindicated.

### IMMUNE DEFICIENCY

Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with bOPV according to standard schedules. However, the vaccine is contraindicated in those with primary immune deficiency disease or suppressed immune response from medication, leukemia, lymphoma or generalized malignancy.

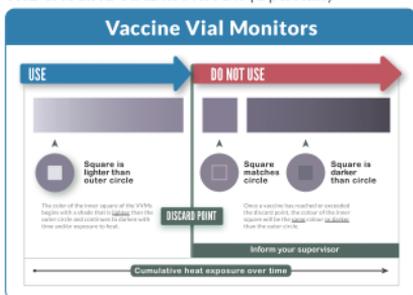
## STORAGE

Vaccine is potent if stored at minus 20°C or below until the expiry date indicated on the vaccine vial label. It can be stored for up to six months between +2°C and +8°C, or can be re-frozen at minus 20°C for up to six months.

## PRESENTATION

The vaccine comes in glass vials of 20 doses.

## THE VACCINE VIAL MONITOR (Optional)

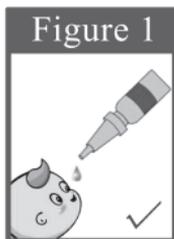


Vaccine Vial Monitors (VVMs) are part of the label on supplied through Beijing Institute of Biological Products Co., Ltd. The colour dot which appears on the label of the vial is a VVM. This is a time temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level. The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.

## INSTRUCTIONS FOR USE:

The vial must first be shaken gently to avoid foaming, but sufficiently to obtain a homogeneous mixture of the contents. Remove the flip top tear down aluminium seal, the rubber cap and fix the pre-sterilized plastic dropper supplied along with the vial. Gently press infant's cheeks by both sides to make his/her mouth open, hold the vial inverted in tilted position (at an angle about 45 degrees) and gently squeeze the middle of the plastic dropper to continuously expel two drops [equal to 0.1ml] of the vaccine on the tongue near the throat.

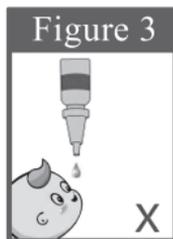
## Directions for use of dropper during vaccine delivery



Hold the vial in tilted position during vaccine delivery into the mouth



Do not hold the vial horizontally for vaccine delivery into the mouth



Do not hold the vial vertically for vaccine delivery into the mouth

## Directions for the dropper

1. Dropper should be discarded with the vaccine vial as re-use of droppers from one vial to another may lead to crack and leakage.
2. First remove the dropper cap and then slightly tap the dropper, ensure the air in the tip of dropper is expelled and full of vaccine liquid. The vial is always held in tilted position (ref. figure 1, at an angle about 45 degrees) for vaccine delivery.
3. Press the mist dropper gently just above the delivery nozzle with soft part of the fingers avoiding nail contact.
4. Bring vial along with dropper to upright position after delivery of each dose.
5. Put the nozzle cover back on the dropper when there is some time elapsed between two consecutive vaccine deliveries.
6. Discard the dropper if the nozzle is contaminated.



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