health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Ms NVB Lephatsoana
The Biovac Institute
The Vaccine Bureau
106 16th Road
Midrand
JOHANNESBURG
1685

Dear Ms Lephatsoana

Section 21 Authorization for Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial 2mL

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Bivalent Oral Poliomyelitis Vaccine 20-Dose Vial**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

8. The full quantities imported in terms of this Section 21authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent over stocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **15 January 2025**.

Table 1: Provincial estimates

Province	Six Months Estimate
Correctional Services	0
EC	12 300
FS	7 300
GP	35 400
KZN	34 400
LP	20 000
MP	12 800
NC	2 000
NW	8 300
WC	17 500
Total	**150 000**

Yours sincerely

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 18/7/2024

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

Section 21 Response Letter

7/15/2024 3:47 PM

Khadija Jamaloodien

National Department of Health
Dr AB Xuma Building
1112 Voortrekker Rd
Pretoria Townlands 351-JR
Pretoria
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965):

Your application dated **7/15/2024 12:40 PM** refers

A. ***STATUS: Approved***
B. ***APPLICANT: Khadija Jamaloodien***
C. ***IMPORTING COMPANY: The Biovac Institute***
D. ***PATIENT/(S):***
E. ***UNREGISTERED MEDICINES:***

GENERIC NAME: Poliomyelitis Vaccine Oral Bivalent Type 1 & 3 (Sabin strain) Live Attenuated

TRADE NAME: Bivalent Oral Poliomyelitis Vaccine Type 1 & 3

F. ***QUANTITY: Bivalent Oral Poliomyelitis Vaccine Type 1 & 3 20-Dose Vial x 150 000 vials***

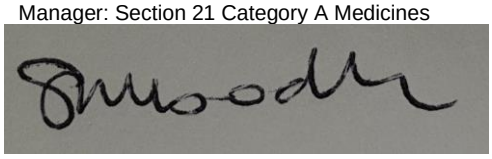
G. ***LETTER NUMBER: B-28989***

Section 21 authorization letters are valid for a period of six months from the letter date, unless otherwise specified.

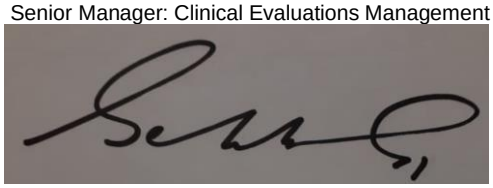
Comments:

Yours faithfully,

Dr S Munbodh
Manager: Section 21 Category A Medicines



T Sehloho
Senior Manager: Clinical Evaluations Management



health
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REQUEST FOR QUOTATION FORM

- **Instruction to complete this Request for Quotation (RFQ)**
  PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
  PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
  THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- **THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL		SECTION 21	X	**S21RFQ133**
QUOTE ENQUIRY DATE	**06/05/2024**	QUOTE CLOSING DATE			**15/05/2024**
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE *(SCM Practitioner to Specify if applicable)*					

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo		
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za		
PHONE No.	**012 395 9539**	FAX No.	**N/A**

PRODUCT INFORMATION

DESCRIPTION PER MPC	**POLIOMYLITIS ORAL BIVALENT VACCINE 20 DOSE 3ML (Bivalent Oral Polio Vaccine 3mL 20 Dropper)**		
TRADE DESCRIPTION	BIVALENT ORAL POLIOMYELITIS VACCINE Types 1 & 3		
UNIT OF MEASURE	**1's**	PACK or BOX (*SIZE/ QUANTITY*)	50's
QUANTITY REQUIRED	**150000 Vials**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

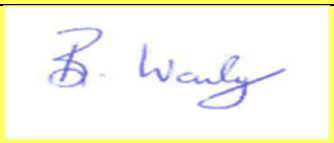
SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	THE BIOLOGICALS AND VACCINES INSTITTUTE OF SOUTHERN AFRICA			
SUPPLIER NUMBER	MAAA0070728			
SECURITY CODE	42132397-91c5-429b-b85a-72b6fb26bf99			
SUPPLIER CODE (NDoH)	**VOSM1**			
CONTACT PERSON 1	NAME	**Berniece Warley**		
	PHONE	**021-5145000**	FAX	**n/a**
	MOBILE	0837082810		
	E-MAIL	**berniecew@biovac.co.za**		
CONTACT PERSON 2	NAME	**Mamorena Mohatla**		
	PHONE	**+27 10 045 2496**		

	MOBILE	**0835730920**
	E-MAIL	**Mamorenam@biovac.co,za**

QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R106.27	TOTAL PRICE (INCL. DELIVERY & VAT)	R106.27
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS	Manufacturer has indicated that bOPV can be delivered ex origin upon product release in August 2024, and subject to 15 working days after awarding of the RFQ and receipt of S21 approval. SAHPRA and NCL release will be required which have normal timelines of 4 to 5 weeks. NDoH will have to motivate directly to SAHPRA for expedited release if bOPV is need for provinces urgently.		
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD			
NORMAL LEAD/DELIVERY TIME			

DEVIATION TO SPECIFICATION
COMMENTS: None

DECLARATION BY SUPPLIER	
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.	
NAME	**Berniece Warley**
CAPACITY	**Head of Sales**
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*	
DATE	**15/05/2024**

Please submit quotations to **Section21Quotes@health.gov.za**

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Central Supplier Database Summary Report (CSD)
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)

All of the above is required to expedite the process in considering the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

NB:

- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ.
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices must please be submitted in two decimals.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

Português

VACINA BIVALENTE ORAL CONTRA A POLIOMIELITE DOS TIPOS 1 & 3

gotas

DESCRIÇÃO
A vacina oral da poliomielite tipos ao vivo 1 & 3 (bOPV) é uma vacina bivalente contendo as suspensões de vírus de poliomielite tipos 1 e 3 atenuadas (cepas de Sabin) preparadas em células de rim de macaco primário. Cada dose (2 gotas = 0,1 ml) contém não inferior a $10^{6.0}$ unidades infectantes do tipo 1 e $10^{5.8}$ do tipo 3. Sacarose é usado como um estabilizador. bOPV pode conter vestígios de não mais de 2 mcg do eritromicina e não superior a 10 mcg do canamicina.

ADMINISTRAÇÃO
bOPV só deve ser administrado por via oral. Duas gotas são entregues diretamente para a boca do frasco múltidose por conta-gotas. Tenha cuidado para não contaminar um conta-gotas do múltidose com saliva do vacinado.

Uma vez aberto, frascos de múltidoses devem ser mantidos entre 2ºC e 8ºC. Frascos de múltidoses de bOPV do qual uma ou mais doses de vacina foram removidos durante uma sessão de imunização podem ser utilizados em sessões de imunização subseqüente para até um máximo de 4 semanas, desde que todas as seguintes condições forem atendidas (conforme descrito na declaração de política de OMS): Política de Frasco de Múltidoses (MDVP), WHO/IVB/14.07)) :

- A vacina é atualmente precalificada pela OMS;
- A vacina é aprovada para uso por até 28 dias após a abertura do frasco, conforme determinado pela OMS;
- Não passou o a data de expiração da vacina;
- O frasco de vacina tem sido, e continuará a ser armazenado em OMS ou temperaturas recomendadas do fabricante; Além disso, o Monitor de Frasco de Vacina (MFV), se ligado, não é passado seu ponto de descarte (ver figura).

CALENDÁRIO DE IMUNIZAÇÃO
bOPV é indicada para imunização ativa em todos os grupos de idade contra infecções causadas pelo vírus da poliomielite do tipo 1 e 3.
O calendário de imunização deve estar em conformidade com as recomendações nacionais.
bOPV pode ser dada de forma segura e eficaz ao mesmo tempo como sarampo, rubéola, caxumba, DTP, DT, TT, Td, BCG, hepatite B, Haemophillus influenzae tipo b, vacina contra febre amarela, IPV (vacina de poliomielite inactivada) e suplementação de vitamina A.

EFEITOS COLATERAIS
Na maioria dos casos não existem efeitos colaterais. Muito raramente, pode haver paralisia associada a vacina (um caso por 1 milhão doses administradas). Pessoas em contato com uma criança recentemente vacinado muito raramente podem estar em risco de poliomielite paralítica associada a vacina.

ADVERTÊNCIAS ESPECIAIS E PRECAUÇÕES DE UTILIZAÇÃO
Em caso de diarréia, a dose recebida não será contabilizada como parte do calendário de imunização e isso deve ser repetido após a recuperação.

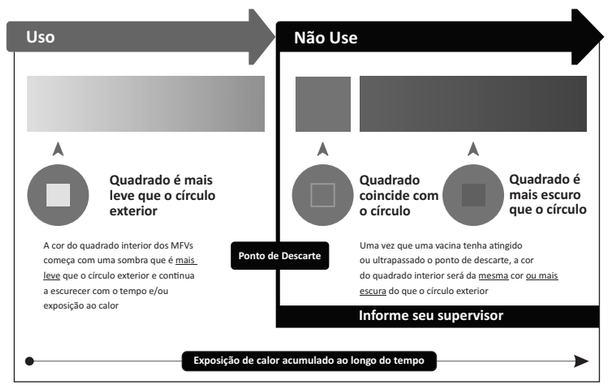
CONTRA-INDICAÇÕES
Sem efeitos adversos são produzidos dando a bOPV para uma criança doente.

Deficiência Imunológica
Indivíduos infectados com o Vírus da Imunodeficiência Humana (VIH), assintomática e sintomática, devem ser imunizados com bOPV de acordo com horários padrão. No entanto, a vacina é contra-indicada em pacientes com doença de deficiência imunológica primária ou a resposta imune suprimido de medicação, leucemia, linfoma ou malignidade generalizada.

ARMAZENAMENTO
A vacina é potente se armazenado em não superior a - 20ºC até a data de expiração indicada no rótulo do frasco. Pode ser armazenado por até seis meses entre+ 2ºC e + 8ºC.
A vacina pode apresentar uma coloração variando de amarelo claro a vermelho claro, devido a uma variação ligeira de pH; no entanto, isso não afeta a qualidade da vacinado.

APRESENTAÇÃO
A vacina vem em frascos de 10 e 20 doses.

Monitores de Frasco de Vacina



Os Monitores de Frascos de Vacina (MFV) fazem parte da etiqueta da bOPV, fornecida por TempTime. O ponto colorido que aparece na etiqueta do frasco é um MFV. Este ponto é um ponto sensível ao tempo e à temperatura que dá uma indicação do calor cumulativo ao qual o frasco tenha sido exposto. Isto averte os utilizadores quando a exposiçao ao calor possa ter degradado a vacina além de um nível aceitável.

A interpretação dos MFV é muito simples. Concentre no quadrado central. A cor do quadrado mudará progressivamente. Desde que a cor deste quadrado seja mais clara do que a cor do círculo, a vacina pode ser usada. Desde que a cor do quadrado central tenha a mesma coloração do que o círculo, ou também uma coloração mais escura do que a cor do círculo, o frasco deve ser descartado.

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Jl. Pasteur no. 28 - Bandung 40161 - Indonesia
PO Box 1136, Tel. +62 22 2033755, Fax. +62 22 2041306
www.biofarma.co.id

Русский

ПЕРОРАЛЬНАЯ ВІВАЛЕНТНАЯ ПОЛИОВАКЦИНА ТИПА 1 & 3

Капли

ОПИСАНИЕ
Вакцина состоит из живых, аттенуированных штаммов Сэбина вируса полиомиелита 1 и 3 типов, выращенного на культуре почек африканских зеленых мартышек. Каждая доза (2 капли = 0,1 мл) содержит не менее $10^{6.0}$ инфекционных единиц для первого типа и $10^{5.8}$ для третьего типа. Используют сахарозу в качестве стабилизатора. ОПВ может содержать следовые количества не более 2 мкг эритромицин и не более чем на 10 мкг канамицина.

ПРИМЕНЕНИЕ
Вакцина предназначена для перорального применения. Две капли поставляются прямо в рот из многодозового флакона с капельницей. Уход должны быть приняты, чтобы не загрязнить мультидозовую капельницу с слюны вакцинируемого.
После вскрытия, Многодозовые флакона должны храниться в пределах от + 2°С до + 8°С. Многодозовые флакона ОПВ из которых один или несколько доз вакцины были удалены во время иммунизации может быть использован при проведении иммунизации в течение максимум 4 недели, при условии, что все следующие условия (как написано в политического заявлении ВОЗ: Политики Многодозовых флаконов (MDVP), ВОЗ / IVB / 14.07):

- Вакцина в настоящее время является предквалификационной в отборе ВОЗа;
- Вакцина утверждена для использования в течение 28 дней после вскрытия флакона, как определил ВОЗ;
- Срок годности вакцины не истек;
- Флакон Вакцина была и будет по-прежнему сохраняются в ВОЗ или рекомендованными производителем температурах; Кроме того, флакон с вакциной монитор (ФТИ), если она установлена, не мимо его сброса точки (см рисунок).

Плановые прививки
ОПВ указывается для активной иммунизации всех возрастных групп против инфекции, вызванные вирусами полиомиелита типа 1 и 3.

Делается согласно Национальному календарю профилактических прививок России.

ОПВ можно вводить одновременно со всеми препаратами из национального календаря профилактических прививок в один день например как корь, краснуха, эпидемический паротит, ТТ, АДС, БЦЖ, гепатит В, гемофильной инфекции типа В, вакцина против желтой лихорадки, ИПВ (инактивированная вакцина полиомиелита) и витамина А.

ПОБОЧНЫЕ ЭФФЕКТЫ

Реакция на введение вакцины практически отсутствует. Крайнюю редкость как у привитых, так и у лиц, контактных с привитыми, представляют вакциноассоциированные заболевания, которые наблюдаются не чаще, чем 1 случай на 1 миллиона привитых детей.

СПЕЦИАЛЬНЫЕ ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ ПО ИСПОЛЬЗОВАНИЮ.
В случае диареи, полученная доза не будет учитываться в качестве части иммунизации и она должна быть повторена после восстановления.

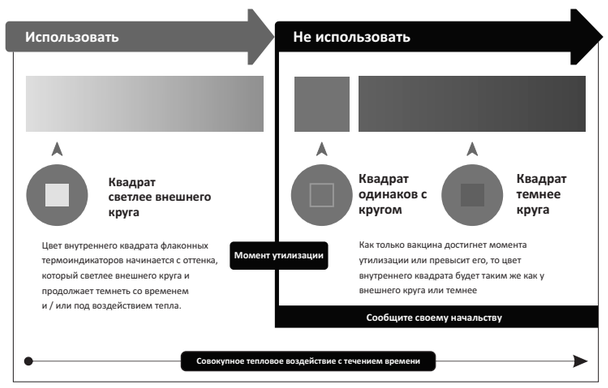
Противопоказание
Не будет побочные эффекта, давая ОПВ больным ребенкам.

Иммунодефицит
Лиц, инфицированных вирусом иммунодефицита человека (ВИЧ), и бессимптомные и симптоматические, должны быть иммунизированы ОПВ в соответствии со стандартными графиками. Тем не менее, вакцина противопоказана у пациентов с первичной болезни иммунодефицита или подавленной иммунной реакции от лекарств, лейкоз, лимфома или обобщенного злокачественности..

УСЛОВИЯ ХРАНЕНИЯ
Вакцина является мощным если сохраняется в амороженном виде при температуре минус -20°С до конца срока годности написан на флаконе.
Можно сохранить до 6 месяцев в при температуре +2°С и +8°С.
Вакцина может представлено в разных цветах от светло-желтого до светло-красного, в связи с небольшим изменением pH, однако это не влияет на качество вакцины.

ФОРМА ВЫПУСКА
ПО 10 и 20 доз во флаконе

Флаконные термоиндикаторы



Установка флакона вакцины (УФИ) это часть на колпачке вакцины bOPV снабжена Temp Time.Цвет точки появляющаяся на этикетке флакона это УФВ. Это представляет времени-температуры чувствительную точку при условии и указании куммулативной теплоты на которой был экспонирован флакон. Это предупреждает конец последнего употребления когда выставление на теплоту деградирует вакцину до прелёмого уровня.

Интерпретация УФИ простая. Фокус на цвет внутренного квадрата будет изменятся постепенно. Если цвет этого квадрата светлее чем круга, вакцина можно употребляться. Если цвет внутреннего квадрата имеет такой же цвет или темнее чем внешнего круга, флакон обьязательно выбросить.

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PO Box 1136, Tel. +62 22 2033755, Fax. +62 22 2041306
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■ **Product information** ■ **Informação sobre o produto** ■ **Информации о продукте**
■ **Información acerca del producto** ■ **Information concernnant le produit**

- ☑ **BIVALENT ORAL POLIOMYELITIS VACCINE TYPES 1 & 3**
- ☑ **VACCIN BIVALENT ORAL CONTRE LA POLIOMYELITE DE TYPES 1 & 3**
- ☑ **VACUNA BIVALENTE ORAL ANTI POLIOMIELÍTICA DEL TIPO 1 & 3**
- ☑ **VACINA BIVALENTE ORAL CONTRA A POLIOMIELITE DOS TIPOS 1 & 3**
- ☑ **ПЕРОРАЛЬНАЯ ВІВАЛЕНТНАЯ ПОЛИОВАКЦИНА ТИПА 1 & 3**

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PO Box 1136, Tel. +62 22 2033755, Fax. +62 22 2041306
www.biofarma.co.id

020619

biofarma	Manufactured	: PT Bio Farma (Persero)	The final dimension of folding	: 120 x 38.75 mm	
	Address	: Jl. Pasteur No 28 Bandung 40161	Leaflet folding	: 5x Folding	
	Product Name	: Leaflet Vaksin bOPV 5 Language	Color	: 2 Color	
	Material	: HVS 60 gsm	PMS Black U PMS Red 032 U		
	Dimension	: 360 x 310 mm, ± 2 mm	120 mm 38.75 mm		
	Scale	: 100 %			
	Edition	: 020619			
	Note	:			

English

BIVALENT ORAL POLIOMYELITIS VACCINE TYPES 1 & 3

drops

DESCRIPTION
The live types 1 & 3 oral polio vaccine (bOPV) is a bivalent vaccine containing suspensions of types 1 and 3 attenuated poliomyelitis viruses (Sabin strains) prepared in primary monkey kidney cell. Each dose (2 drops = 0.1 ml) contains not less than $10^{6.0}$ infective units of type 1 and $10^{5.8}$ of type 3. Sucrose is used as a stabilizer. bOPV may contain trace amounts of not more than 2 mcg erythromycin and not more than 10 mcg kanamycin.

ADMINISTRATION
bOPV must only be administered orally. Two drops are delivered directly into the mouth from the multidose vial by dropper. Care should be taken not to contaminate a multidose dropper with saliva of the vaccinee.

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), 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's recommended temperatures; furthermore, the vaccine vial monitor (VVM), if attached, is not past its discard point (see figure).

IMMUNIZATION SCHEDULE
bOPV is indicated for active immunization in all age groups against infection caused by poliomyelitis viruses of Type 1 and 3.

The immunization schedule must be in accordance with the national recommendations.

bOPV can be given safely and effectively at the same time as measles, rubella , mumps, DTP, DT, TT, Td, BCG, hepatitis B, Haemophillus influenzae type b, yellow fever vaccine, IPV (inactivated Polio Vaccine) and vitamin A supplementation.

SIDE EFFECTS
In the vast majority of cases there are no side effects. Very rarely, there may be vaccine-associated paralysis (one case per 1 million doses administered). Persons in close contact with a recently vaccinated child may very rarely be at risk of vaccine-associated paralytic poliomyelitis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
In case of diarrhoea, the dose received will not be counted as part of the immunization schedule and it should be repeated after recovery.

CONTRAINDICATIONS
No adverse effects are produced by giving bOPV to a sick child.

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, leukaemia, lymphoma or generalized malignancy.

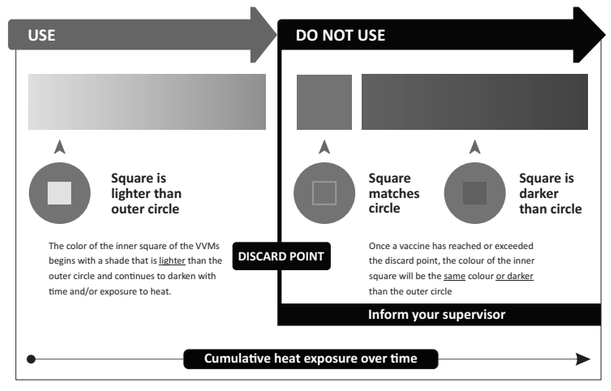
STORAGE
Vaccine is potent if stored at not higher than -20°C until the expiry date indicated on the vial.

It can be stored for up to six months between +2°C and +8°C.

The vaccine may present a colour varying from light yellow to light red, due to a slight variation of pH; however this does not affect the quality of the vaccine.

PRESENTATION
The vaccine comes in vials of 10 and 20 doses.

Vaccine Vial Monitors



Vaccine Vial Monitors (VVMs) are part of the label on all bOPV supply through Temp Time. 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.

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Français

VACCIN BIVALENT ORAL CONTRE LA POLIOMYELITE DE TYPES 1 & 3

gouttes

DESCRIPTION
Le vaccin oral de la poliomyélite de types 1 & 3 (bOPV) est un vaccin bivalent contenant une suspension du virus atténué de types 1 & 3 de la poliomyélite (souche Sabin). Ces virus sont préparés dans des cellules primaires de rein de singe. Chaque dose (2 gouttes = 0,1 ml) ne contient pas moins de $10^{6.0}$unités infectieuses de type 1 et $10^{5.8}$ de type 3. Le saccharose est utilisé comme stabilisateur. Le bOPV peut contenir une certaine quantité d'érythromycine n'excédant pas 2 mcg et de kanamycine n'excédant pas 10 mcg.

MODE ET VOIE D'ADMINISTRATION
Le bOPV doit être uniquement administré par voie orale. A l'aide d'un flacon multidose muni d'un compte-gouttes, on dépose deux gouttes directement dans la bouche. Pour les enfants, il est préférable d'éviter l'éventuel goût amer en plaçant préalablement les gouttes sur un morceau de sucre ou dans du sirop. Il faut veiller à ne pas contaminer le compte-gouttes avec la salive de la personne se faisant vacciner.

Une fois ouverts, les flacons multidoses doivent être conservés à une température comprise entre +2° et +8°C. Les flacons multidoses de VPOb à partir de laquelle une ou plusieurs doses de vaccin ont été enlevées au cours d'une séance de vaccination peuvent être utilisés pour des séances de vaccination ultérieures jusqu'à un maximum de 4 semaines , à condition que tous les critères suivants sont remplis (comme décrit dans la Déclaration de politique générale de l'OMS relative aux flacons multidoses, OMS/IVB/14.07):

- Le vaccin est actuellement préqualifié par l' OMS;
- Son utilisation jusqu'à 28 jours après l'ouverture du flacon est homologuée, conformément à ce qui a été déterminé par l'OMS;
- La date de péremption du vaccin n'est pas dépassée;
- Le flacon de vaccin a été et continuera d'être conservé aux températures recommandées par l'OMS ou le fabricant ; de plus, la pastille de contrôle du vaccin, s'il en est muni, est visible sur *l'étiquette du vaccin* et n'a pas dépassé le point limite d'utilisation, et le vaccin n'a pas été endommagé par le gel (voir figure).

MODALITES DE VACCINATION
VPOb est indiqué pour l'immunisation active dans tous les groupes d'âge contre les infections causées par les virus de la poliomyélite de type 1 et 3.
Le calendrier de vaccination doit être en conformité avec les recommandations nationales.
VPOb peut être administré en toute sécurité et efficacement dans le même temps que les vaccins contre la rougeole , la rubéole, les oreillons, DTP , DT , TT , Td , BCG , l'hépatite B , Haemophillus influenzae de type b , la vaccination contre la fièvre jaune , l'IPV (vaccin antipoliomyélitique inactivé) et supplémentation en vitamine A.

EFFETS SECONDAIRES
Dans la grande majorité des cas, aucun effet secondaire n'a été rapporté en ce qui concerne l'OPV trivalent, qui contient le même composant bOPV. Très rarement, l'usage du vaccin contre la Polio est susceptible de provoquer des paralysies (moins d'un cas par million de doses administrées).

Il est possible, mais très rare, que des personnes puissent être atteintes de paralysie poliomyélitique due à un contact direct avec un enfant récemment vacciné.

AVERTISSEMENTS ET PRÉCAUTIONS SPÉCIALES
En cas de diarrhée, la dose reçue ne sera pas comptabilisée dans le programme d'immunisation et il faudra la renouveler après guérison.

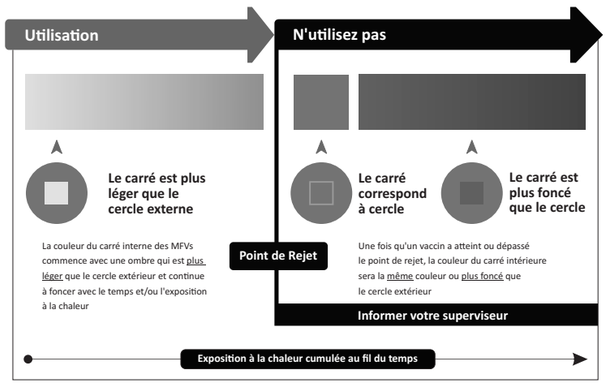
CONTRE-INDICATIONS
On n'observe aucun effet secondaire si on administre le vaccin à un enfant malade.

Immuno-déficience
Les personnes infectées par le virus de l'immuno-déficience humaine (VIH), aussi bien asymptomatique que symptomatique, doivent être immunisées conformément au calendrier de vaccination contre le bOPV. Cependant, le vaccin est contre-indiqué chez les personnes qui ont une immuno-déficience primaire ou une réponse immunitaire supprimée par les médicaments, leucémie, lymphome ou cancer généralisé.

STOCKAGE
Le vaccin reste efficace tant qu'il est conservé à une température inférieure à -20°C jusqu'à expiration de la date d'utilisation indiquée sur le flacon. Le vaccin peut en outre être stocké pendant 6 mois à une température comprise entre +2° et +8°C.
Le vaccin peut présenter une couleur allant du jaune clair au rouge clair due à une faible variation du pH; néanmoins cela n'affecte pas la qualité du vaccin.

PRESENTATION
Le vaccin se présente en flacons de 10 et 20 doses.

Moniteurs du Flacon du Vaccin



Les pastilles de contrôle du vaccin (PCV) font parties de l' étiquette de tout VPOb, fournie par Temptime. La pastille témoin (le cercle) qui apparaît sur l'étiquette du flacon est une PCV. C'est un témoin sensible à la température et au temps qui fournit des informations sur la chaleur accumulée à laquelle le flacon été exposé. Il permet de prévenir de la fin d'utilisation quand l'exposition à la chaleur risque d'avoir dégradé le vaccin au-delà de la limite acceptable.

L'interprétation de la PCV est simple. En observant le carré central, on peut remarquer que la couleur change progressivement. Tant que la couleur de ce carré est plus claire que celle du cercle, alors le vaccin peut être utilisé. Dès que la couleur du carré a la même couleur que celle du cercle ou si elle est plus foncée que celle du cercle, alors il faut mettre le flacon au rebut.

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Español

VACUNA BIVALENTE ORAL ANTI POLIOMIELÍTICA DEL TIPO 1 & 3

gotas

DESCRIPCIÓN
La vacuna de la polio oral vivo tipos 1 & 3 (bOPV) es una vacuna bivalente que contienen suspensiones de virus de la poliomielitis tipos 1 y 3 atenuados (cepas de Sabin) preparadas en células de riñón de mono primaria. Cada dosis (2 gotas = 0,1 ml) contiene no menos de $10^{6.0}$unidades infecciosas de tipo 1 y $10^{5.8}$ de tipo 3. Sacarosa es utilizada como un estabilizador. bOPV puede contener cantidad de trazas de no más de 2 mcg de eritromicina y no más de 10 mcg de kanamicina.

ADMINISTRACIÓN
bOPV sólo debe administrarse por vía oral. Dos gotas se entregan directamente en la boca del frasco multidosis por cuentagotas. Debe tener cuidado de no contaminar un cuentagotas de multidosis con la saliva del vacunado.
Una vez abiertos, los frascos multidosis deben ser conservados entre 2°C y 8°C. Los frascos multidosis de bOPV de que se han quitado una o más dosis de vacuna durante una sesión de inmunización pueden utilizarse en sesiones subsecuentes de inmunización hasta un máximo de 4 semanas, siempre que cumplan con las siguientes condiciones (como se describe en la declaración de política de la OMS):Política de Frasco de Multidosis (MDVP), WHO/IVB/14.07):

- La vacuna actualmente está precalificada por la OMS;
- La vacuna está aprobada para uso hasta 28 días después de abrir el frasco, según lo determinado por la OMS;
- No ha pasado la fecha de caducidad de la vacuna;
- El frasco de la vacuna ha sido, y seguirá almacenarse a OMS o a las temperaturas recomendadas del fabricante; Además, el monitor de frasco de vacuna (MFV), si sujetado, no es más allá de su punto de descarte (ver figura).

CALENDARIO DE INMUNIZACIÓN
bOPV está indicado para la inmunización activa de todas las edades contra la infección causada por el virus de la poliomielitis tipo 1 y 3.
El calendario de inmunización debe ajustarse a las recomendaciones nacionales.
bOPV puede administrarse con seguridad y eficacia al mismo tiempo como sarampión, rubéola, paperas, DTP, DT, TT, Td, BCG, hepatitis B, Haemophillus influenzae tipo b, vacuna contra la fiebre amarilla, IPV (vacuna inactivada de la Polio) y suplementos de vitamina A.

EFECTOS SECUNDARIOS
En la mayoria de los casos no hay efectos secundarios. Muy raramente, puede haber parálisis asociada a vacuna (un caso por 1 millón de dosis administradas). Las personas en contacto cercano con niños recientemente vacunados muy raramente pueden estar en riesgo de poliomielitis paralítica asociada a vacuna.

AVISOS ESPECIALES Y PRECAUCIONES DE USO
En caso de diarrea, la dosis recibida no se contará como parte del calendario de inmunización y debe repetirse después de la recuperación.

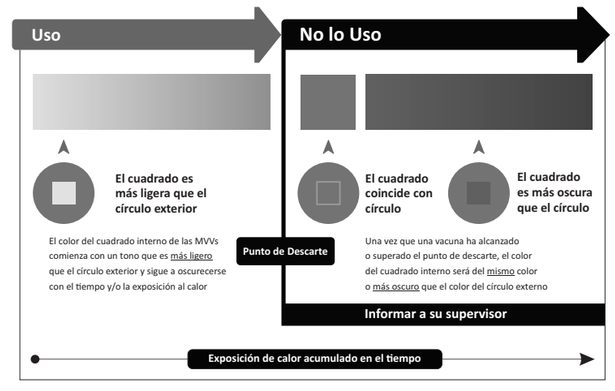
CONTRAINDICACIONES
Ningunos efectos adversos se producen dando bOPV a un niño enfermo.

Deficiencia Inmune
Individuos infectados con el Virus de la Inmunodeficiencia Humana (VIH), ambos asintomático y sintomático, deben ser inmunizados con la vacuna bOPV según horarios estándar. Sin embargo, la vacuna está contraindicada en aquellas personas con la enfermedad de deficiencia inmune primaria o la respuesta inmune suprimido de medicamentos, leucemia, linfoma o malignidad generalizado.

ALMACENAMIENTO
La vacuna es potente si se almacena a no superior de -20°C hasta la fecha de caducidad indicada en el frasco.
Puede ser almacenado hasta seis meses entre +2°C y +8°C.
La vacuna puede presentar un color varía de amarillo claro a rojo claro, debido a una variación ligera del pH; sin embargo esto no afecta la calidad de la vacuna.

PRESENTACIÓN
La vacuna viene en los frascos de 10 y 20 dosis.

Monitores de Vacuna Vial



Los Monitores de Frascos de Vacuna (MFV) forman parte de la etiqueta de todas las bOPV, suministrados por TempTime. El cuadrado de color que aparece en la etiqueta del frasco es un MFV. Este es sensible al tiempo y a la temperatura, y da una indicación del calor acumulado, al cual el frasco ha sido expuesto. Advierte y previene el uso cuando la exposición al calor puede haber degradado la vacuna mas allá de un nivel admisible.

La interpretación del MFV es muy fácil. Concéntrese en el cuadrado central. El color del cuadrado cambiará progresivamente. Si el color de este cuadrado es más claro que el color del círculo, la vacuna puede ser empleada. Si el color del cuadrado central tiene la misma coloración que el círculo, o también una coloración más oscura que el círculo, el frasco debe ser descartado.

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Manufactured	: PT Bio Farma (Persero)	The final dimension of folding	: 120 x 38.75 mm
Address	: Jl. Pasteur No 28 Bandung 40161	Leaflet folding	: 5x Folding
Product Name	: Leaflet Vaksin bOPV 5 Language	Color	: 2 Color
Material	: HVS 60 gsm	PMS Black U PMS Red 032 U	
Dimension	: 360 x 310 mm, ± 2 mm	120 mm 38.75 mm	
Scale	: 100 %		
Edition	: 020619		
Note	:		

020622
BF-08

BIVALENT ORAL POLIOMYELITIS VACCINE

20 DOSES

Types 1 & 3
(Sabin)

biofarma

Manufactured by:
PT Bio Farma (Persero)
Jl Pasteur No 28,
Bandung-INDONESIA

50 Vials of 2 mL
Oral Drops Suspension
1 dose: 0.1 mL
For oral use only
The vaccine is not to be injected

Pemerian: Cairan berwarna kuning muda sampai merah muda.
Dibuat pada sel primer ginjal kera.

Komposisi: tiap dosis (2 tetes = 0,1 mL) mengandung:
Zat aktif: virus Polio (**sabin strain**) hidup yang dilemahkan
tipe 1 ≥ $10^{6.0}$ $CCID_{50}$, tipe 3 ≥ $10^{5.8}$ $CCID_{50}$
Zat tambahan:
- Eritromisin tidak lebih dari 2 mcg.
- Kanamisin tidak lebih dari 10 mcg.
- Sukrosa 35% (v/v) sebagai stabiliser.

Simpan pada suhu -20°C. Bila disimpan antara +2°C dan +8°C, vaksin stabil selama 6 bulan. Lindungi dari cahaya.
Keterangan lebih lanjut lihat leaflet.
Harus dengan resep dokter.

Appearance: Light yellow to light red solution.
Prepared in primary monkey kidney cell.

Composition: each dose (2 drops = 0.1 mL) contains:
Active ingredient: live attenuated Polio virus (sabin strain)
type 1 ≥ $10^{6.0}$ $CCID_{50}$, type 3 ≥ $10^{5.8}$ $CCID_{50}$
Excipients:
- Erythromycin not more than 2 mcg.
- Kanamycin not more than 10 mcg.
- Sucrose 35% (v/v) as stabilizer.

Store at -20°C. It can be stored up to 6 months at temperature between +2°C and +8°C. Protect from light.
For further information see the leaflet inside.
On medical prescription only.

Vaccin Bivalent Oral
Contre la Polio de Types 1 & 3
Présentation pharmaceutique:
Solution jaune clair-rouge clair.
Preparé dans des cellules primaires de reins de singes.
Composition: chaque dose (2 gouttes = 0,1 mL) contient: Ingrédient actif: virus atténué de la poliomyélite (souche de sabin)
du type 1 ≥ $10^{6.0}$ $CCID_{50}$, type 3 ≥ $10^{5.8}$ $CCID_{50}$
Excipients:
- Erythromycine: pas plus de 2 mcg.
- Kanamycine: pas plus de 10 mcg.
- Sucrose: 35% (v/v) comme stabilisateur.
Ne peut être délivré que sur ordonnance médicale.

50 flacons de 2 mL
1 dose: 0,1 mL
Ne peut être administré que par voie buccale
Le vaccin ne peut pas être injecté

Conserver à -20°C.
Le vaccin peut être conservé durant six mois à une température comprise entre +2°C et +8°C.

Conserver à l'abri de la lumière.

De plus amples renseignements sont contenus dans la brochure ci-incluse.

Reg. No.: GKL1502907036A1
Manufactured by: PT Bio Farma (Persero)
Jl Pasteur No 28, Bandung-INDONESIA

BATCH NO.:
SERIAL NO.:
MFG. DATE:
EXP. DATE:

GTIN:08994957000065

Vacuna Bivalent Oral
Anti Poliomielitis del Tipos 1 & 3
Presentación farmacéutica:
solución amarilla clara - roja clara.
Preparada en células primarias de riñones de monos.
Composición: cada dosis (2 gotas = 0,1 mL) contiene: Ingrediente activo: virus atenuado de la poliomielitis (linaje de Sabin) del tipo 1 ≥ $10^{6.0}$ $CCID_{50}$, tipo 3 ≥ $10^{5.8}$ $CCID_{50}$
Excipientes:
- Eritromicina: no más de 2 mcg.
- Kanamicina: no más de 10 mcg.
- Sucrosa: 35% (v/v) como estabilizador.
Se vende solamente con receta médica.

50 frascos de 2 mL
1 dosis: 0,1 mL
Se utiliza solamente por vía buccal
La vacuna no puede ser inyectada

Conservar a una temperatura de -20°C.
La vacuna puede ser conservada durante seis meses a una temperatura de entre +2°C et +8°C.

Conservar fuera da luz.

Más informaciones son contenidas en el volante incluso.

biofarma	Manufactured : PT Bio Farma (Persero)	Area printing dimension : 20 x 50 mm
	Address : Jl. Pasteur No 28 Bandung 40161	Pattern : Lock bottom carton
	Product : Box BOPV 20 Doses (1 box isi 50 vial @ 2 mL)	Color : 2 Color
	Material : Ivory 350 gsm	PMS Red 032 C
	Dimension : 170 x 85 x 38 mm, ± 2 mm	PMS Black C
	Scale : 100 %	
	Edition : 020622	
	Kode Artwork : BF-08	