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IMPORTANT MEDICINES INFORMATION
SECTION 36 APPROVAL - MEASBIO® Vaccine

NL/154

26 June 2023

Dear Healthcare Professional

To ensure continuity of supply of MeasBio® for use in South Africa, Biovac has obtained a Section 36 exemption from the South African Health Products Regulatory Authority [SAHPRA] to supply MeasBio® vaccine and the diluent for MeasBio® packed in Indonesian National Agency for Food and Drug Control [NA-DFC] approved labelling with the UNICEF Leaflet. This vaccine is manufactured at the same facility as the South African labelled MeasBio®.

As directed by SAHPRA, Biovac would like to inform you that the outer cartons, immediate labels and professional information (PI) will be that of the Indonesian/UNICEF product, and therefore it is important to refer to the South African PI/PIL available on the SAHPRA PI/PIL repository and can be accessed on: [PI and PIL Repository \(sahpra.org.za\)](https://sahpra.org.za)

Table 1: Imported MeasBio® Vaccine and Diluent for MeasBio® batches

Product Details	Lot No	Expiry Date
Measles Vaccine	2506722	December-2025
Measles Vaccine	2506922	December-2025
Measles Vaccine	2507022	January-2026
Measles Vaccine	2507122	January-2026
Measles Vaccine	2507222	January-2026
Measles Vaccine	2507322	January-2026
Measles Vaccine	2507422	January-2026
Measles Vaccine Diluent	9910723	February-2028
Measles Vaccine Diluent	9910323	February-2028
Measles Vaccine Diluent	9910823	February-2028
Measles Vaccine Diluent	9910523	February-2028
Measles Vaccine Diluent	9910623	February-2028
Measles Vaccine Diluent	9910723	February-2028

Table 2: Noticeable labelling differences between the Indonesian/UNICEF vaccine and the SA vaccine includes:

	South African vaccine and diluent	Imported Indonesian/UNICEF vaccine and diluent
Proprietary Name	MeasBio® Diluent for MeasBio®	Measles Vaccine Measles Vaccine Diluent
Languages: <ul style="list-style-type: none">• Label• Carton• Professional Information	English/Afrikaans English/Afrikaans English/Afrikaans	English/Bahasa (local Indonesian language) English/Bahasa (local Indonesian language) English, French, Greek, Spanish, Portuguese and Indonesian Bahasa.

Scheduling status	S2	On medical prescription only
Registration Number	43/30.1/0541	GKL9302900544A1
Interactions with other childhood vaccines.	<p>RSA approved PI states:</p> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>MEASBIO® IS NOT TO BE USED WITH OTHER CHILDHOOD VACCINES</p> </div>	<p>UNICEF Leaflet states: Measles vaccine can be given safely and effectively simultaneously with DTP, Td, TT, BCG, polio (OPV and IPV), <i>Haemophilus influenzae</i> type b, hepatitis B, and yellow fever vaccines and vitamin A supplementation.</p> <p>Kindly refer to National Department of Health Circular dated 02.02.2023 dealing with CO-ADMINISTRATION OF MEASLES VACCINES WITH OTHER VACCINES DURING THE NATIONAL MEASLES CAMPAIGN AND MEASLES OUTBREAK RESPONSE IN CHILDREN 9 MONTHS AND OLDER.</p> <p>This Circular states "During routine immunisation services it is not recommended for the MeasBio® vaccine to be combined with other vaccines. However, the World Health Organisation (WHO) recommends that MeasBio® vaccine can safely be co-administered with other vaccines from 9 months of age. Therefore, during the outbreak response and national measles campaign MeasBio® vaccine can be co-administered with other vaccines given to children 9 months and older including the human papillomavirus (HPV), Tetanus/reduced diphtheria (Td), and Comirnaty® (Pfizer COVID-19) vaccines."</p>

Advice to healthcare professionals


- If a healthcare professional is involved in the EPI routine vaccination of infants against measles (outside of the current measles campaign) he/she should refer to the **attached RSA approved MeasBio® PI/PIL** for information. The UNICEF PI/PIL is to be used for the outbreak response and national measles campaign purposes only.
- Healthcare professionals are urged to report any adverse drug reactions (ADRs), or product quality issues (including batch details) associated with the use of MeasBio® to Biovac via telephone: 021 514 5000 or via e-mail: DrugSafety@biovac.co.za, or to SAHPRA via the eReporting link available on the SAHPRA website (www.sahpra.org.za).
- Alternatively healthcare professionals may complete the ADR reporting form accessible via the SAHPRA website and email it to adr@sahpra.org.za. Additionally, reporting can be done via the MedSafety App. The App can be downloaded onto a smart phone via google play or app store. For more information on Med Safety App kindly visit SAHPRA website.

For further information, please contact:

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Yours faithfully,

THE BIOVAC INSTITUTE



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Responsible Pharmacist