

IMPORTANT MEDICINES INFORMATION
SECTION 36 APPROVAL - MEASBIO® Vaccine

31 March 2023

Dear Healthcare Professional

South Africa is currently experiencing measles outbreaks in several provinces. In order to curb this outbreak and interrupt the transmission of measles, the Department of Health has extended the target population during the planned national measles vaccination campaign from children under the age of 5 years to all children under 15 years.

Kindly note, that in order to ensure continuity of supply of MeasBio® in South Africa for this widespread campaign, 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 \(sahpra.org.za\)](http://sahpra.org.za)

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

Product Details	Lot No	Expiry Date
Measles Vaccine	2506122	Nov-2025
Measles Vaccine	2506222	Dec-2025
Measles Vaccine	2506322	Dec-2025
Measles Vaccine Diluent	9914822	Sep-2027
Measles Vaccine Diluent	9914922	Oct-2027
Measles Vaccine Diluent	9915022	Oct-2027

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: • 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
	RSA approved PI states:	UNICEF Leaflet states: Measles vaccine can be given safely and effectively simultaneously with DTP,

Interactions with other childhood vaccines.	MeasBio® is not to be used with other childhood vaccines	Td, TT, BCG, polio (OPV and IPV), <i>Haemophilus influenzae</i> type b, hepatitis B, and yellow fever vaccines and vitamin A supplementation. 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. These 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.”
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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

Electronically signed by:
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Nthabiseng Lephatoana
Responsible Pharmacist