

UPDATE TO CIRCULAR CMU 04/2025: INTERRUPTION IN THE SUPPLY OF BETAMETHASONE DISODIUM PHOSPHATE 4MG/ML; INJECTION; 1ML FROM PHARMA-Q (PTY) LTD AND THE SUPPLY OF AN ALTERNATIVE PRODUCT FROM ORGANON SA (PTY) LTD



Private Bag X828, PRETORIA, 0001.DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands
Directorate: Affordable Medicines Tel: (012) 395 8130



351-JR, PRETORIA 0187

Circular no. CMU 07/2025

UPDATE TO CIRCULAR CMU 04/2025: INTERRUPTION IN THE SUPPLY OF BETAMETHASONE DISODIUM PHOSPHATE 4MG/ML; INJECTION; 1ML FROM PHARMA-Q (PTY) LTD AND THE SUPPLY OF AN ALTERNATIVE PRODUCT FROM ORGANON SA (PTY) LTD

This is an update to the published circular ref: CMU 04/2025 disseminated on 26 February 2025, see Annexure 1. The circular update outlines the Standard Treatment Guidelines (STG) alternatives of Betamethasone Disodium Phosphate; 4mg/ml; injection; 1 ml which is currently out of stock and the recommended routes of administration.

The National Department of Health (NDoH) has sourced stock of **Betamethasone disodium phosphate 3mg & Betamethasone acetate 3mg per ml; injection; 1ml** on a Provincial Procurement on Quotation (PPQ) from Organon SA (Pty) Ltd.

Please note that betamethasone disodium phosphate 3mg & betamethasone acetate 3mg per ml; 1ml injection is **not for intravenous or subcutaneous use**.

Please see the therapeutic alternatives for betamethasone disodium phosphate 4MG/ML; 1ML injection and the recommended routes of administration below:

Indication: Level (Adults)	Hospital	Therapeutic alternatives to Betamethasone Disodium Phosphate; 4mg/ml injection:
Chapter 6: Obstetrics 6.11.1 PRETERM LABOUR (PTL) AND PRETERM PRELABOUR RUPTURE OF MEMBRANES (PPROM)		<p>To improve fetal lung maturity at 26–34 weeks *:</p> <ul style="list-style-type: none"> Betamethasone, IM, 12 mg, 2 doses 24 hours apart <p><i>The combination of betamethasone disodium phosphate 3mg & betamethasone acetate 3mg per 1ml is equivalent to 6mg per ml of betamethasone. (12mg requires 2ml of betamethasone disodium phosphate 3mg & betamethasone acetate 3mg).</i></p> <p>If betamethasone is not available:</p> <ul style="list-style-type: none"> Dexamethasone, IM, 8 mg, 3 doses 8 hours apart.
Chapter 14: Neurological disorders 14.12.1 BRAIN OEDEMA DUE TO TUMOURS AND INFLAMMATION		<p>Patients with primary brain tumours or brain metastases should be considered for definitive treatment of the tumour, which includes surgery and/or radiotherapy.</p> <ul style="list-style-type: none"> Dexamethasone, IV, 4 mg 6 hourly, initially. <p>OR</p> <p>Betamethasone, oral, 4 mg 6 hours.</p> <ul style="list-style-type: none"> Discontinue if no response has occurred after 48 hours. Taper dose according to response and duration of therapy.

***NOTE: Only Intramuscular Betamethasone/Dexamethasone injections are indicated to improve fetal lung maturity.**

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Please see the procurement details of the alternatives recommended for use during the out-of-stock period below:

NSN	Product Description	Supplier Name
180075543	Betamethasone disodium phosphate 3mg & Betamethasone acetate 3mg per ml; injection; 1ml	Organon SA (Pty) Ltd
180075759	Dexamethasone; 4mg/ml; injection; 1 ml	Trinity Pharma (Pty) Ltd
222000141	Betamethasone; 500mcg; Tablet; 100 Tablets	Pharmacare Ltd

Provinces and Healthcare facilities are kindly requested to distribute and communicate this information with all healthcare professionals and relevant stakeholders.

Comments may be submitted *via* e-mail:

Stock queries:

Ms. Babalwa Melitafa

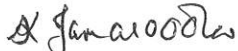
E-mail: Babalwa.Melitafa@health.gov.za

Clinical queries:

Essential Drug Programme

E-mail: SAEDP@health.gov.za

Kind regards,



MS K JAMALOODIEN

CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT

DATE: 03/4/2025

UPDATE TO CIRCULAR CMU 04/2025: INTERRUPTION IN THE SUPPLY OF BETAMETHASONE DISODIUM PHOSPHATE 4MG/ML; INJECTION; 1ML FROM PHARMA-Q (PTY) LTD AND THE SUPPLY OF AN ALTERNATIVE PRODUCT FROM ORGANON SA (PTY) LTD

ANNEXURE 1



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Circular no. CMU 04/2025

NOTICE: INTERRUPTION IN THE SUPPLY OF BETAMETHASONE DISODIUM PHOSPHATE 4MG/ML; INJECTION; 1ML FROM PHARMA-Q (PTY) LTD AND THE SUPPLY OF AN ALTERNATIVE PRODUCT FROM ORGANON SA (PTY) LTD

Betamethasone is included in the Adult Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) for a number of indications including brain oedema and premature labour (for improvement of foetal lung maturity).

Pharma-Q (Pty) Ltd, one of the contracted suppliers of Betamethasone Disodium Phosphate; 4mg/ml; injection; 1 ml on the HP06-2024 SVP tender, is currently unable to manufacture this product due to regulatory constraints with their aseptic filling line.

The National Department of Health (NdoH) sourced stock of Betamethasone disodium phosphate 3mg & Betamethasone acetate 3mg per ml; injection; 1ml on a Provincial Procurement on Quotation (PPQ) from Organon SA (Pty) Ltd as outlined in the table below. Organon SA (Pty) Ltd has agreed to manufacture additional quantities for the public sector of the Betamethasone disodium phosphate 3mg & Betamethasone acetate 3mg per ml; injection; 1ml to help mitigate the shortage of this item across provinces.

Orders can be placed with Organon SA (Pty) Ltd to ensure uninterrupted supply of the above-mentioned item.

NSN	Product Description	Supplier Name
180075543	Betamethasone disodium phosphate 3mg & Betamethasone acetate 3mg per ml; injection; 1ml	Organon SA (Pty) Ltd

Provinces and Healthcare facilities are kindly requested to distribute and communicate this information with all healthcare professionals and relevant stakeholders.

Comments may be submitted via e-mail:

Stock queries:

Ms. Babalwa Melitafa

E-mail: Babalwa.Melitafa@health.gov.za

Clinical queries:

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Kind regards,

MS K JAMALOODIEN

CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT

DATE: 26 February 2025