



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Ms Z Makeleni
Rx Medicals (Pty) Ltd
Unit A1, Building 2
Devonbosch
Bottelary Road
Koelenhof, Stellenbosch
Cape Town
7600

Dear Ms Z Makeleni

Section 21 Authorization for Dexamethasone 0.5mg Tablets 100's

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

- **Dexamethasone 0.5mg Tablets 100's**

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.

Section 21 Authorisation re Dexamethasone 0.5mg Tablets 100's 06102026-1

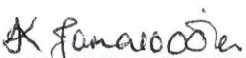
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover 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 overstocking 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 **01 April 2027**.

Table 1: Provincial uptake

Province	Six Months Estimate
Correctional Services	0
EC-MT	0
EC-PE	300
FS	360
GP	330
KZN	1 200
LP	60
MP	0
NC	50
NW	36
SAMHS	10
WC	1 200
Total	3 546

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 8/10/2026

Section 21 Outcome Letter

2026-10-06

Ms Khadija Jamaloodien

Voortrekker Road, National Department Of Health, Voortrekker Road, Pretoria Townlands 351-Jr,
Pretoria, South Africa, Voortrekker Road, Pretoria, Gauteng, Pretoria, Gauteng, South Africa, 0157

Pretoria, Gauteng

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

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

Your application dated **2026-10-01** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: RX MEDICALS (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1**
- E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT):**
Dexamethasone
- F. TRADE NAME: Dexamethasone Tablets BP 0.5 mg**
- G. QUANTITY: 3504 Packs (100)**

H. LETTER NUMBER: S2100038713

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

A progress report must be submitted once treatment is completed or on a reauthorization request

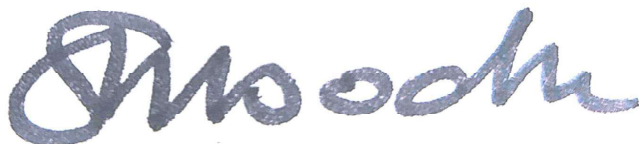
Comments:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines

A handwritten signature in blue ink, appearing to read 'Shyamli Munbodh', enclosed within a thin black rectangular border.



health

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0187 Tel (012) 395 8000, Fax (012) 395 8918

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	S21RFQ187/2026
QUOTE ENQUIRY DATE	10/09/2026	QUOTE CLOSING DATE			17/09/2026
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

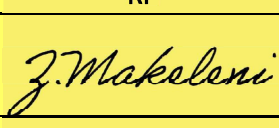
PRODUCT INFORMATION

DESCRIPTION PER MPC	Dexamethasone 0.5mg Tablets 100's		
TRADE DESCRIPTION			
UNIT OF MEASURE	100's	PACK or BOX (<u>SIZE/ QUANTITY</u>)	1
QUANTITY REQUIRED	3 500		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

DID YOU BID ITEM FOR TENDER	YES	X	NO		IF NO, WHY	
COMPANY NAME	RXMEDICALS PTY LTD					
SUPPLIER NUMBER	MAAA0298118					
SECURITY CODE						
SUPPLIER CODE (NDoH)						
CONTACT PERSON 1	NAME	Zintle Makeleni				
	PHONE	0789895573			FAX	0866203472
	MOBILE	0789895573				
	E-MAIL	zintlem@rxmedicals.co.za				
CONTACT PERSON 2	NAME	Xolani Njovane				
	PHONE	0741501904				

	MOBILE	0741501904	
	E-MAIL	xolanin@rxmedicals.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R93.84	TOTAL PRICE (INCL. DELIVERY & VAT)	R328,440.00
VOLUMES AVAILABLE – 14DAYS	3500		
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE – 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 DAYS		
NORMAL LEAD/DELIVERY TIME	3days		
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS:			
<u>DECLARATION BY SUPPLIER</u>			
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	Zintle Makeleni		
CAPACITY	RP		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	17/09/2026		
<u>PROVINCIAL ESTIMATES</u>			
Province	Six Months Estimate		
DCS	0		
EC-MT	0		
EC-PE	300		
FS	360		
GP	330		
KZN	1 200		
LP	60		

MP	0
NC	50
NW	36
SAMHS	10
WC	1 200
<i>Please submit quotations to Buhle.Mbongo@health.gov.za</i>	

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

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- 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 supplier submitting the quotation must be the same entity which the provinces will place their orders
- 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.
- The confirmation letter from manufacturer to Supply South Africa with Bivalent oral Poliomyelitis Vaccine (bOPV) must be provided (only in cases of Bivalent oral Poliomyelitis Vaccine 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 and in ZAR.
- 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
- CSD must be updated for the current month of the RFQ date.
- **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**

Leaflet size: 166 x 170 mm
Text matter source : IDR

DEXAMETHASONE

TABLETS BP

0.5 MG

GENERAL INFORMATION :

ENDOCRINE SYSTEM: It is selective and very potent glucocorticoid. It causes suppression of pituitary adrenal axis.

POISONING, DRUG DEPENDANCE & EMERGENCY MEDICINES: It is an emergency medicine.

COMPOSITION:

Each tablet contains:

Dexamethasone BP 0.5 mg

Excipients q. s.

CATEGORY:

Glucocorticoid.

MOA:

ENDOCRINE SYSTEM: After binding to the receptor, the steroid receptor complex binds to chromatin and stimulates the formation of mRNA. The mRNA stimulates the synthesis of enzymes.

The antiinflammatory action is due to inhibition of prostaglandin and leukotriene synthesis.

The actions of glucocorticoids are (a) increased gluconeogenesis. (b) increased lipolysis (c) increased liver stores of glycogen (d) CNS effects, euphoria (e) increased haemoglobin synthesis (f) restrict capillary permeability and maintenance of cardiovascular function (g) cause normal skeletal muscular function (h) antiinflammatory action (i) suppression of immune response (j) stabilize lysosomal membranes (k) antiallergic action.

INDICATIONS:

Shock due to trauma. Allergic emergencies. Overwhelming infections (with specific antibiotics). Adrenal crisis. Rheumatoid arthritis. Asthma. Nephrotic syndrome. Suppression of inflammation in eye disorders. Various types of eczemas including infantile eczema, dermatitis including otitis externa, lichen planus, anal and vulval pruritus, neurodermatitis.

DOSAGE AND ADMINISTRATION:

ENDOCRINE SYSTEM: Adults: 4-20mg repeated as necessary.

Children: 0.1-0.5mg/kg/24 hours.

EMERGENCY MEDICINE: Adults: 4-20mg repeated as necessary.

Children: 0.1-0.5mg/kg/24 hours.

CONTRAINDICATIONS:

ENDOCRINE SYSTEM: Diabetes mellitus, psychosis, osteoporosis, tuberculosis, congestive heart failure, renal failure.

ADVERSE EFFECTS:

ENDOCRINE SYSTEM: Hyperglycaemia, glucosuria, fatigue, weakness, delayed wound healing, cushing's habitus, hirsutism, fragile skin, telangiectasis.

SPECIAL PRECAUTIONS:

ENDOCRINE SYSTEM: Glaucoma, epilepsy, hypertension, hepatic dysfunction, may reduce response of pituitary adrenal axis to stress.

INTERACTIONS:

ENDOCRINE SYSTEM: Barbiturates: Decreases efficacy of dexamethasone.

Carbamazepine, Primidone: Decreases efficacy.

Oral contraceptives: Increases efficacy of dexamethasone.

Ephedrine: Decrease efficacy of dexamethasone.

Oestrogens: Decrease efficacy of dexamethasone

Hydantoins: Decrease efficacy of dexamethasone

Ketoconazole: Increase efficacy of dexamethasone

Rifampicin: Decreases efficacy.

Dexamethasone effects the actions of the following:

Anticholinesterases: Efficacy antagonised in myasthenia gravis.

Oral anticoagulants: Altered response.

Cyclosporine: Increased cyclosporine efficacy leading to enhanced toxicity.

Digitalis glycosides: Increased toxicity associated with hypokalaemia.

Isoniazid: Decreased serum levels of isoniazid.

Salicylates: Decreased serum levels of salicylates.

Diuretics: Increase efficacy may cause increased hypokalaemia and increased hyperglycemia.

Non-depolarising muscle relaxants: Altered response.

Theophyllines: Altered response of either agent.

IUCDs: contraceptive failure.

Lab. Tests: a) Increases serum cholesterol levels.

Increases urine glucose levels.

Decreases Thyroid I131 uptake. Decreases T3 serum levels. Decreases serum potassium.

Brain Scan: Dexamethasone alters result of brain scan due to decreased uptake of radioactive material.

STORAGE:

Store between temperature 8°C to 25°C. Protect from light.

Keep out of the reach of children.

PRESENTATION:

Blister strip of 10 tablets and 10 strips are packed in a printed carton.

Manufactured by :

KWALITY PHARMACEUTICALS LTD.

Nag Kalan, Majitha Road, Amritsar - India



Component : Carton
Dimension : 94 x 38 x 51 mm
Colour : CMYK
GSM : 320 GSM ITC Cyber XL
Varnish / coating: U.V. coating

10 X 10 Tablets

DEXAMETHASONE

TABLETS BP

0.5 MG

Administration way: **Oral**

**Anti-inflammatory
Corticosteroid**

Composition:
Each tablet contains:
Dexamethasone BP 0.5 mg
Excipients q.s.

Dosage:
As directed by the Physician.

Storage:
Store between temperature 8°C to 25°C.
Protect from light.

Keep out of the reach of children.

10 X 10 Tablets

DEXAMETHASONE

TABLETS BP

0.5 MG

Administration way: **Oral**

**Anti-inflammatory
Corticosteroid**

Mfg. Lic. No.: 1800-OSP

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road,
Amritsar - India

Batch Printing Area

DEXAMETHASONE

TABLETS BP

0.5 MG

Administration way: **Oral**

Mfg. Lic. No.: 1800-OSP

Manufactured by:
KWALITY PHARMACEUTICALS LTD.
Nag Kalan, Majitha Road,
Amritsar - India

Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2017 to Jan/2020

Check List for Labeling													Formulation No.:		
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength, Volume & Packing	STORAGE	
9708/1	English														
Matching all parameters between Box and Label															
Matching the parameter with label of leader brand															
Previous specimen artwork : NEW					Designed by : Prabhjeet Singh			Order Quantity		Party Name		Packing			
Checked by :		Approved by :		Authorized by:		Party Approval		180000		Prime Pharma					
Production Incharge		QC Incharge		Q.A.		M.D.				Card Board used for carton :					
										☐ G/B ☐ W/B ☐ I.T.C. ☐ Pearl					



Component : BLISTER FOIL
Dimension : 184 mm (87 x 34 mm)
Colour : CMYK
Thickness 0.25 micron
DULL SIDE PRINTING

DEXAMETHASONE TABLETS BP 0.5 MG		Keep out of the reach of children. Administration way: Oral Mfg. Lic. No.: 1800-OSP
Composition: Each tablet contains: Dexamethasone BP 0.5 mg Excipients q.s. Dosage: As directed by the Physician. Storage: Store between temperature 8°C to 25°C. Protect from light.		Manufactured by: KWALITY PHARMACEUTICALS LTD. Nag Kalan, Majitha Road, Amritsar - India
DEXAMETHASONE TABLETS BP 0.5 MG	DEXAMETHASONE TABLETS BP 0.5 MG	DEXAMETHASONE TABLETS BP 0.5 MG

Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2017 to Jan/2020

Check List for Labeling													Formulation No.:		
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Neutral Code	Packing	Category	Mfg. Name	Reg.No.	Check Order for strength, Volume & Packing	STORAGE	
9708/1	English														
Matching all parameters between Box and Label															
Matching the parameter with label of leader brand															
Previous specimen artwork : NEW					Designed by : Prabhjeet Singh			Order Quantity	Party Name		Packing				
Checked by :		Approved by :		Authorized by :		Party Approval		180000	Prime Pharma						
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton : ☐ G/B ☐ W/B ☐ I.T.C. ☐ Pearl							