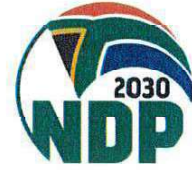




health

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

Mr J Elugubanti
RBC Pharmaceuticals (Pty) Ltd
23 Kiaat Street
Erf 926
Extension 7
Noordwyk
Midrand
1687

Dear Mr Elugubanti

Section 21 Authorization for SALBUTAMOL 5MG/2.5ML Nebuliser Solution

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

- **Salbutamol 5mg/2.5mL Nebuliser Solution**

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 Salbutamol Nebuliser Solution 5mg/2.5mL 11062026-2

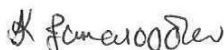
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorization must be accounted for.
9. Note that this authorization DOES NOT cover 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 **10 December 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	0
EC-PE	10 000
FS	2 000
GP	0
KZN	3 000
LP	0
MP	34 560
NC	0
NW	0
SAMHS	150
WC	5 000
Total	54 710

Yours sincerely



KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT

DATE: 11/6/2026

Section 21 Outcome Letter

2026-06-10

Ms Khadija Jamaloodien

1112 Voortrekker Road

Pretoria

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 **2026-06-09** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: RBC PHARMACEUTICALS (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 9**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Salbutamol Nebuliser Solution 5 mg**
- G. QUANTITY: 54432 Packs (10)**

H. LETTER NUMBER: S2100031004

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

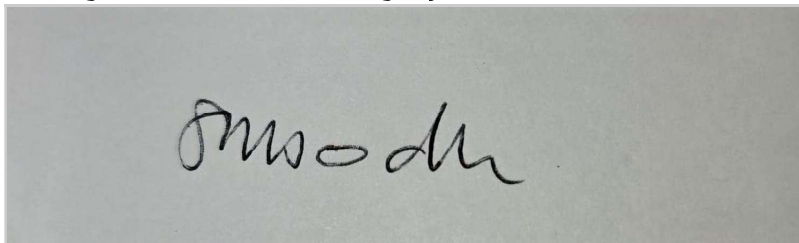
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Ms Moropa' written in a cursive style.

Ms Mahlodi Moropa

Final Approver

S2100031004



SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083


A rectangular box containing a handwritten signature in black ink. The signature is stylized and appears to be 'M. P. P.' or similar, with a large initial 'M' and a horizontal line crossing through it.

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	S21RFQ175/2026
QUOTE ENQUIRY DATE	17/04/2026	QUOTE CLOSING DATE			30/04/2026
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)					
<u>REQUESTING INSTITUTION CONTACT DETAILS</u>					
NAME OF REQUESTOR	Babalwa Melitafa				
EMAIL ADDRESS	Babalwa.Melitafa@health.gov.za				
PHONE No.	0835352209	FAX No.		N/A	
<u>PRODUCT INFORMATION</u>					
DESCRIPTION PER MPC	Salbutamol Nebules 0.5% 5MG/2.5ML Inhalation Solution 2.5ml				
TRADE DESCRIPTION					
UNIT OF MEASURE	ml	PACK or BOX (<u>SIZE/ QUANTITY</u>)		2.5ml	
QUANTITY REQUIRED	72260				
<u>TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER</u>					
<u>SUPPLIER CONTACT DETAILS (as per CSD)</u>					
DID YOU BID ITEM FOR TENDER	YES		NO	X	IF NO, WHY
COMPANY NAME	RBC Pharmaceuticals (Pty) Ltd				
SUPPLIER NUMBER	MAAA0791389				
SECURITY CODE	0d814e95-9947-41a3-9b43-1763ff7d837f				
SUPPLIER CODE (NDoH)	VN6L3				
CONTACT PERSON 1	NAME	Jitendranadh Elugubanti			
	PHONE	010 224 0999	FAX		
	MOBILE	0628044801			
	E-MAIL	jitendranadh@rbcpharma.com			
CONTACT PERSON 2	NAME	Kishore Badavath			
	PHONE	010 224 0999			

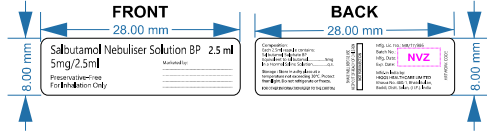
	MOBILE	0628044801	
	E-MAIL	info@rbcpharma.com	
<u>QUOTE DETAILS</u>			
PRICE PER UNIT (INCL. VAT)	R4.03	TOTAL PRICE (INCL. DELIVERY & VAT)	R291207.80
VOLUMES AVAILABLE – 14DAYS	-		
VOLUMES AVAILABLE – 21DAYS	30000		
VOLUMES AVAILABLE – 28DAYS	42260		
VOLUMES AVAILABLE – 35DAYS	-		
VOLUMES AVAILABLE – 42DAYS	-		
VOLUMES AVAILABLE – 49DAYS	-		
VOLUMES AVAILABLE – 56DAYS	-		
VOLUMES AVAILABLE – 112DAYS	-		
QUOTE VALIDITY PERIOD	Quotation Validity Period is 60 days		
NORMAL LEAD/DELIVERY TIME	Once Order confirmed, Delivery time is within 14 days		
<u>DEVIATION TO SPECIFICATION</u>			
<p>COMMENTS: <i>Generic name: Salbutamol Nebuliser Solution 2.5mg/2.5mL</i> <i>Brand name - Salbutamol Nebuliser Solution 2.5mg/2.5mL</i> <i>Country of Origin – INDIA.</i> Manufacturer: HIGGS HEALTHCARE LIMITED. Website: https://higgs.co.in/</p>			
<u>DECLARATION BY SUPPLIER</u>			
<p>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.</p>			
NAME	Jitendranadh Elugubanti		
CAPACITY	Manager		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	30.04.2026		

PROVINCIAL ESTIMATES	
Province	Six Months Estimate
DCS	0
EC-MT	0
EC-PE	10 000
FS	2000
GP	0
KZN	3000
LP	0
MP	34560
NC	0
NW	17550
SAMHS	150
WC	5000

Please submit quotations to Babalwa.Melitafa@health.gov.za

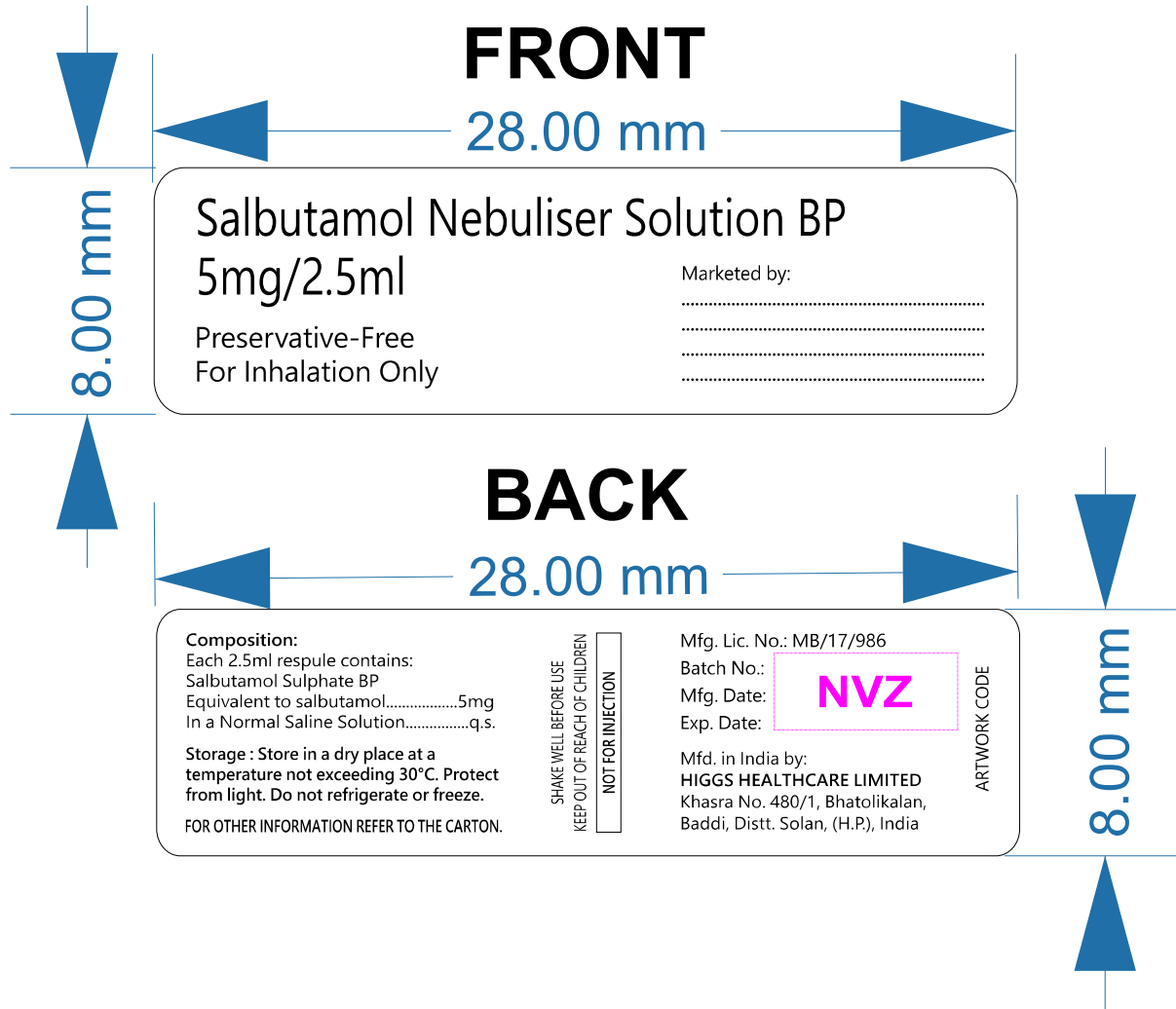


Actual Artwork



Respule Shape : Oval
Substrate :- Chromo Paper
Varnish :- UV
Colour Matching :- As per CDR
Roll form / Sheet Form :- Roll Form
Unwinding Direction :- TO BE CONFIRM
Lo 1 <input type="checkbox"/> Lo 2 <input type="checkbox"/> Lo 3 <input type="checkbox"/> Lo 4 <input type="checkbox"/>

Enlarged Artwork



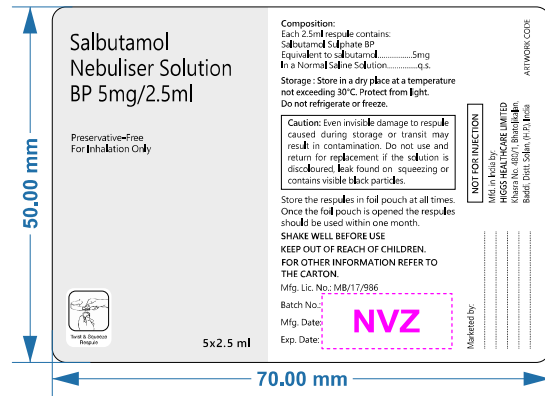
ARTWORK: LABEL

■ BLACK

Product Name	Size (mm)	Artwork Code	Party/Country	Effective Date
SALBUTAMOL 5MG/2.5ML	28x8mm			

Change Made: New artwork for export.	App.by	Prepared by	QC	Production	QA

Actual Artwork



Respule Shape : Oval
Substrate :- Chromo Paper
Varnish :- UV
Colour Matching :- As per CDR
Roll form / Sheet Form :- Roll Form
Unwinding Direction :- TO BE CONFIRM

Enlarged Artwork



ARTWORK: POUCH LABEL

BLACK

Product Name	Size (mm)	Artwork Code	Party/Country	Effective Date
SALBUTAMOL 5MG/2.5ML	50x70mm			
Change Made: New artwork for export.	App.by	Prepared by	QC	Production
				QA

ARTWORK CODE

ARTWORK: CARTON (LOCK BOTTOM CARTON)

■ **BLACK**

Product Name	Size (mm)	Artwork Code	Party/Country	Effective date
SALBUTAMOL 5MG/2.5ML	85x50x140			
Changes made : New artwork for export.				
Specification: ITC Sapphire 300 GSM + UV				
		App. by	QC	QA
		Prepared by	Production	

Composition:
Each 2.5ml respule contains:
Salbutamol Sulphate BP
Equivalent to salbutamol.....5mg
In a Normal Saline Solution.....q.s.

Storage : Store in a dry place at a temperature not exceeding 30°C. Protect from light. Do not refrigerate or freeze.

Caution: Even invisible damage to respule caused during storage or transit, may result in contamination. Do not use and return for replacement if the solution is discoloured, leak found on squeezing or contains visible black particles.

NOT FOR INJECTION

SHAKE WELL BEFORE USE

KEEP OUT OF REACH OF CHILDREN.

Store the respules in foil pouch at all times. Once the foil pouch is opened the respules should be used within one month.

Mfg. Lic. No.: MB/17/986

Batch No.:

NVZ

Mfg. Date:

Exp. Date:

Mfd. in India by:
HIGGS HEALTHCARE LIMITED
Khasra No. 480/1, Bhatoli Kalan,
Baddli, Distt. Solan, (H.P), India

Salbutamol Nebuliser Solution BP 5mg/2.5ml

Preservative-Free
For Inhalation Only



4x5x2.5 ml

85.00 mm

50.00 mm

Salbutamol Nebuliser Solution BP 5mg/2.5ml

Preservative-Free
For Inhalation Only

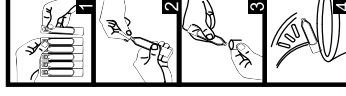


4x5x2.5 ml

Direction for use: The product should be used with a respirator or nebuliser only, under the direction of a Physician. It is not to be injected or administered orally.

Remove a strip of combipack respules from the carton.

Use a fresh respule for each dose.



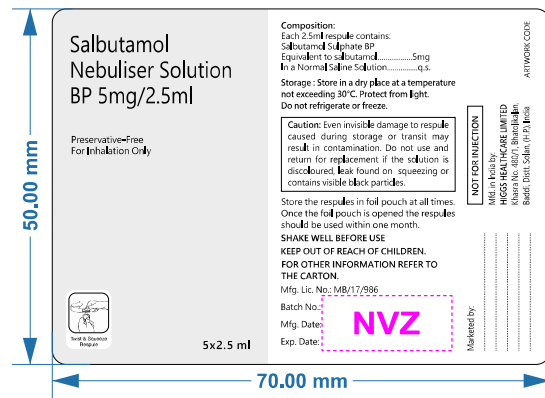
Marketed by:

.....
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50.00 mm

50.00 mm

Actual Artwork



Respule Shape : Oval
Substrate :- Chromo Paper
Varnish :- UV
Colour Matching :- As per CDR
Roll form / Sheet Form :- Roll Form
Unwinding Direction :- TO BE CONFIRM

Enlarged Artwork



ARTWORK: POUCH LABEL

BLACK

Product Name	Size (mm)	Artwork Code	Party/Country	Effective Date
SALBUTAMOL 5MG/2.5ML	50x70mm			
Change Made: New artwork for export.	App.by	Prepared by	QC	Production
				QA

ARTWORK CODE

ARTWORK: CARTON (LOCK BOTTOM CARTON)

BLACK

Product Name	Size (mm)	Artwork Code	Party/Country	Effective date
SALBUTAMOL 5MG/2.5ML	85x50x140			
Changes made : New artwork for export.				
Specification: ITC Sapphire 300 GSM + UV				
		App. by	QC	Production
				QA

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Equivalent to salbutamol.....5mg
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HIGGS HEALTHCARE LIMITED
Khasra No. 480/1, Bhatoli Kalan,
Baddli, Distt. Solan, (H.P.), India

Salbutamol Nebuliser Solution BP 5mg/2.5ml

Preservative-Free
For Inhalation Only



4x5x2.5 ml

85.00 mm

50.00 mm

Salbutamol Nebuliser Solution BP 5mg/2.5ml

Preservative-Free
For Inhalation Only

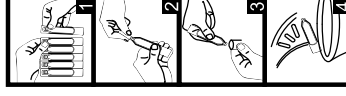


4x5x2.5 ml

Direction for use: The product should be used with a respirator or nebuliser only, under the direction of a Physician. It is not to be injected or administered orally.

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Use a fresh respule for each dose.



Marketed by:

.....
.....
.....

140.00 mm

