



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 2.5MG/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 2.5mg/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 2.5mg/2.5mL 11062026-1

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 **10 December 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	0
EC-PE	10 000
FS	1 000
GP	0
KZN	6 000
LP	0
MP	69 120
NC	0
NW	26 620
SAMHS	18
WC	5 000
Total	117 758

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 11/01/2026

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: 1000**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Salbutamol Nebuliser Solution BP 2.5 mg**
- G. QUANTITY: 118800 Packs (20)**

H. LETTER NUMBER: S2100030981

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

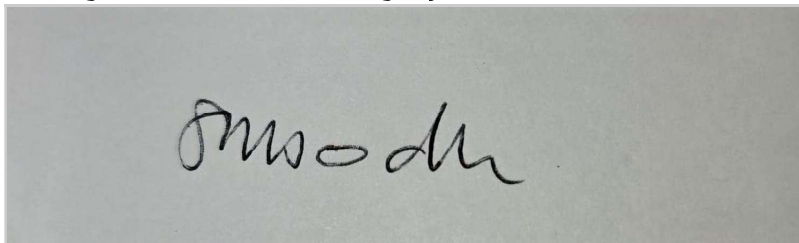
A progress report must be submitted once treatment is completed or on a reauthorization request

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.

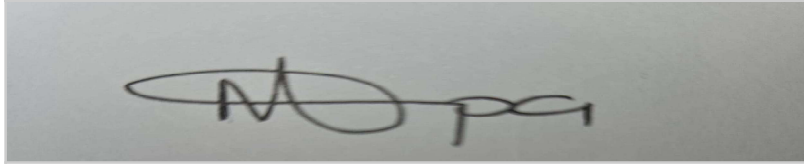
Ms Mahlodi Moropa

Final Approver

S2100030981



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



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	S21RFQ173/2026
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)

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Babalwa Melitafa				
EMAIL ADDRESS	Babalwa.Melitafa@health.gov.za				
PHONE No.	0835352209	FAX No.	N/A		

PRODUCT INFORMATION

DESCRIPTION PER MPC	Salbutamol Nebules 2.5MG/2.5ML Solution				
TRADE DESCRIPTION	SABUPAM 2.5mg/2.5ml				
UNIT OF MEASURE	ml	PACK or BOX (SIZE/ QUANTITY)	2,5ml		
QUANTITY REQUIRED	116758				

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

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

QUOTE DETAILS

PRICE PER UNIT (INCL. VAT)	R3.31	TOTAL PRICE (INCL. DELIVERY & VAT)	R386468.98
VOLUMES AVAILABLE – 14DAYS	-		
VOLUMES AVAILABLE – 21DAYS	40000		
VOLUMES AVAILABLE – 28DAYS	40000		
VOLUMES AVAILABLE – 35DAYS	36758		
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		

DEVIATION TO SPECIFICATION

COMMENTS:

COMMENTS:

Generic name: Salbutamol Nebuliser Solution 5mg/2.5mL


Brand name - Salbutamol Nebuliser Solution 5mg/2.5mL

Country of Origin – INDIA.

Manufacturer: HIGGS HEALTHCARE LIMITED.

Website: <https://higgs.co.in/>**DECLARATION BY SUPPLIER**

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	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	0
GP	0

KZN	6000
LP	0
MP	69120
NC	0
NW	26620
SAMHS	18
WC	5000

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



Patent Information Leaflet
Salbutamol Nebuliser Solution BP 2.5mg/2.5ml
SABUPAM

Read this entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine may have some possible side effects listed in this leaflet. What is in this leaflet?
 1. What Salbutamol Nebuliser Solution BP 2.5mg and what it is used for
 2. What you need to know before you use Salbutamol Nebuliser Solution BP 2.5mg
 3. How to use Salbutamol Nebuliser Solution BP 2.5mg
 4. Possible Side Effects.
 5. How to store Salbutamol Nebuliser Solution BP 2.5mg
 6. Contents of the pack and other information.

1. What Salbutamol Nebuliser Solution BP 2.5mg is and what it is used for
 Salbutamol Nebuliser Solution is a liquid which, when used in a nebulising device, is converted into a mist which can then be inhaled. It contains the active ingredient salbutamol (salbutamol sulfate) which belongs to a group of medicines called beta-2 agonists or bronchodilators. These are used to make breathing easier by relaxing and opening up the airways in the lungs. They are used to treat asthma or other chest conditions (such as asthma or bronchitis) particularly if when no other treatment seem to work. They are also used to treat severe attacks of asthma.

2. What you need to know before you use Salbutamol Nebuliser Solution BP 2.5mg.
 Do not use Salbutamol Nebuliser Solution if:
 - You are allergic to any of the other ingredients of this medicine (listed in Section 6).
 - You are pregnant or breastfeeding.
 - You are on any other medicine which may interact with Salbutamol Nebuliser Solution.
 You are especially at risk of a severe allergic reaction if you have ever had a severe allergic reaction to any other medicine.

Warnings and precautions
 Salbutamol nebuliser solution should be used as required rather than regularly.
 Talk to your doctor, pharmacist or nurse before taking Salbutamol Nebuliser Solution if:
 - You have ever had a severe allergic reaction to any other medicine.
 - You are taking other medicines (such as theophylline) or steroids to treat your asthma.
 - You are taking xanthine derivatives (such as theophylline) or steroids to treat your asthma.
 - You are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.
 - You have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma.
 - You have high blood pressure.
 - You have a slow or irregular heart rate.
 - You are diabetic.
 - You have an overactive thyroid.

Other medicines and Salbutamol Nebuliser Solution BP 2.5mg
 Tell your doctor, pharmacist or nurse if you are taking any other medicines, including medicines obtained without a prescription. This includes herbal remedies. Remember to take these medicines with you if you go to hospital. In particular, tell your doctor, nurse or pharmacist if you are taking:
 - Other medicines for your asthma.
 - Beta-blockers such as propranolol. These are not usually taken with salbutamol.
Salbutamol Nebuliser Solution with food and drink
 You can use Salbutamol Nebuliser Solution at any time of day, with or without food.

Pregnancy, breastfeeding and fertility
 If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.
Driving and using machines
 Salbutamol Nebuliser Solution is not likely to affect your ability to drive or use any tools or machines. You should not drive or use machinery while using the nebuliser as this makes the mist for you to inhale.

3. How to use Salbutamol Nebuliser Solution BP 2.5mg
 Always use your Salbutamol Nebuliser Solution exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.
 Do not mix or swallow the liquid. Salbutamol nebuliser solution should only be inhaled using your nebuliser.
 Do not milk the liquid, or the mist produced by the nebuliser get into your eyes. You can wear glasses or goggles to protect them.
 Your doctor, nurse or pharmacist should show you how to use your medicine.
 Each small plastic container (ampoule) contains some liquid. Do not breathe in through a face mask or mouthpiece.
 Use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.

Adults, adolescents aged 12 years and over and children 4 to 11 years of age
 The usual starting dose is 2.5mg up to 4 times a day, as described in "How to use your Nebuliser". Your doctor may increase the dose to 5mg up to 4 times a day if required.
 Do not use Salbutamol Nebuliser Solution for longer than 14 days unless advised by your doctor. If you have asthma, you should be under the care of a doctor with experience in the management of asthma so that observation in an asthma clinic can be detected and treated without delay.
 Only use the nebuliser recommended by your doctor and supervise your child when they are using the nebuliser.
 Seek urgent medical assistance if the nebuliser medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

Read and follow the instructions on the pharmacist's label. Do not take more doses than your doctor has prescribed or use your nebuliser more often than you are told to.
 If you are using Salbutamol Nebuliser Solution for longer than 14 days, you should be under the care of a doctor with experience in the management of asthma so that observation in an asthma clinic can be detected and treated without delay.
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How to use your Salbutamol Nebuliser
 1. Check the nebuliser and get ready for filling.
 2. Strip the nebuliser and get ready for filling.
 3. Open the lid (wrapping is coming along with the ampoules). Only open when you are ready to use the first ampoule.

3. Take the ampoule strip out of the wrapping and remove the end ampoule by twisting downwards and away from you. Release the unused ampoules back into the lid over-wrap and allow them back into their box.
4. To open the ampoule, hold the body and top of the ampoule securely and then twist the body.
5. Remove the nebuliser container and empty the contents by squeezing slowly.
6. Set up and use the nebuliser as you have been shown.
7. Ensure that any remaining solution left in your nebuliser after use is discarded and your nebuliser is cleaned as recommended.
8. Nebulisers should always be used in a well-ventilated room. Salbutamol Nebuliser Solution is intended to be used unfiltered.

If you have been told by your doctor to dilute Salbutamol Nebuliser Solution, empty the contents of the Ampoule into the nebuliser container, add the amount of sterile, normal saline solution as recommended. Do not use any other liquid. Only open when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again.

If you use more Salbutamol Nebuliser Solution BP 2.5mg than you should
 If you use more than you should, talk to a doctor as soon as possible.
 The following effects may happen:
 - You may feel nervous or jittery.
 - You may feel shaky.
 - You may feel breathless.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.

If you forget to take Salbutamol Nebuliser Solution BP 2.5mg
 If you forget to take your medicine, take it as soon as you remember. If it is close to the time for the next dose, skip the missed dose.
 Do not take a double dose to make up for a forgotten dose.

If you stop using Salbutamol Nebuliser Solution
 Do not stop using salbutamol nebuliser solution without talking to your doctor.
 If you stop using salbutamol nebuliser solution, you may experience some of the following side effects:
 - You may feel your heart beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while.
 - You may feel your heartbeats uneven or give an extra beat.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.

4. Possible Side Effects
 Like all medicines, this medicine can cause side effects, although not everybody gets them. If after using this medicine you immediately experience a worsening of your asthma symptoms or your wheezing gets worse then stop using this medicine and contact your doctor immediately.
 If you get any of the following very rare side effects after taking this medicine you should contact your doctor or hospital emergency department immediately:
 - Any sudden weakness, difficulty in breathing or dizziness.
 - Swelling of the eyelids, face, lips or throat.
 - Collapse or fainting.

Talk to your doctor as soon as possible if:
 - You feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while.
 - You may feel your heartbeats uneven or give an extra beat.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.
 - You may feel dizzy.
 - You may feel tired.
 - You may feel sick.

Common (may affect up to 1 in 10 people)
 Tremor
 Headache
 Dizziness
 Tiredness
 Nausea
 Irritability
 Mouth and throat irritation
 Muscle cramps
 Rare (may affect up to 1 in 1,000 people)
 Low blood potassium level (feeling weak or may cause heart problems to people taking increased blood flow to your extremities (peripheral dilatation)).
 Very rare (may affect up to 1 in 10,000 people)
 Hypersensitivity
 Restlessness or excitability
 Chest pain, especially if you have existing heart disease. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.
 Build-up of lactic acid in your blood. Your doctor will know this from a blood test. This may cause stomach pain, hyper-ventilation, shortness of breath, even though there may be improvement in your wheezing, chest pain and hands. Irregular heartbeat and thirst.
5. How to store Salbutamol Nebuliser Solution BP 2.5mg
 Store below 30°C. Protect from direct sunlight, heat & moisture.
 Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information
 What Salbutamol Nebuliser Solution BP 2.5mg contains
 Salbutamol sulfate 2.5mg
 Equivalent to salbutamol 2.5mg
 In Normal Saline Solution 0.9g
 The other ingredients are sodium chloride, sulphuric acid and water for injections.
 What Salbutamol Nebuliser Solution BP 2.5mg looks like and the content of the pack
 40 x 0.5ml LPS ampoules are packed in a carton along with instructions.
 Mfg. in India by:
HIGGS HEALTHCARE LIMITED
 6/108, NCR, 48011, Bhopal, Madhya Pradesh, India
 Bhopal, Uttar Pradesh, (PIN-482001), India

Marketed & Exported by:

ARTWORK CODE

BLACK

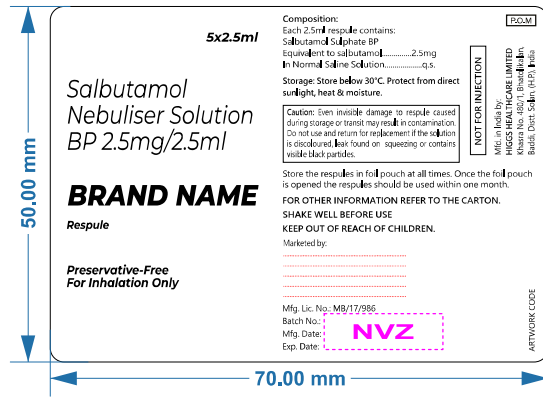
FLAP: 6 FLAP IN HEIGHT.

ARTWORK: INSERT (FRONT & BACK)

Product Name	Size (mm)	Artwork Code	Party/Country	Effective date	PREPARED BY	App. by	QC	PRODUCTION	PACKING	QA
SALBUTAMOL 2.5MG/2.5ML	140x200mm									

CHANGES MADE : NEW ARTWORK FOR EXPORT.

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

COLOR:

Product Name	Size (mm)	Artwork Code	Party/Country			Effective Date	
SALBUTAMOL 2.5MG/2.5ML	50x70mm						
CHANGE MADE: NEW ARTWORK FOR EXPORT.		PREPARED BY	App.by	QC	PRODUCTION	PACKING	QA