



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

Mrs TL Burger  
MC Pharma (Pty) Ltd  
62 Constantia Avenue  
Mnandi  
Centurion  
0157  
Tshwane

Dear Mrs Burger

#### **Section 21 Authorization for PROTAMINE 10MG/ML INJECTION 5ML**

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

- **Protamine 10mg/mL injection 5mL**

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 7<sup>th</sup> of each month, using the attached format of orders received and issues done.

**Section 21 Authorisation re Protamine 10mg/mL INJ 5mL 18112025-1**

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 **18 May 2026**.

**Table 1: Provincial usage**

Province	Six Months Estimate
DSC	0
EC-MT	0
EC-PE	800
FS	1320
GP	3030
KZN	1500
LP	0
MP	85
NC	60
NW	246
SAMHS	50
WC	3600
Total	10 691

Yours sincerely

  
**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 18/11/2025**

## Section 21 Outcome Letter

2025-11-18

Ms Buhle Mbongo

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

### **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 **2025-11-14** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: MC PHARMA (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 5250**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Protamine Sulfate Injection USP 10 mg/mL**
- G. QUANTITY: 10500 Packs (1 )**

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**H. LETTER NUMBER: S2100016014**

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

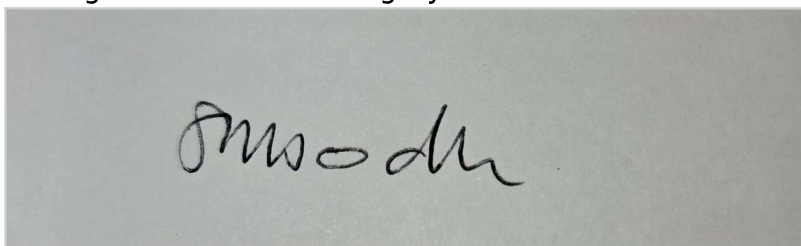
A progress report must be submitted once treatment is completed or on a reauthorization request

**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

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S2100016014



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

A rectangular box containing a handwritten signature in dark ink. The signature is stylized, with a large, loopy initial 'M' or 'N' followed by a series of connected loops and a final vertical stroke.

MC Pharma (Pty) Ltd.  
62 Constantia Avenue,  
Mnandi, Centurion, 0157  
Tel: +27 (0)12 668-3019  
[www.mcpharma.co.za](http://www.mcpharma.co.za)



19 October 2025

**TO: The National Department of Health**

**Directorate: Affordable Medicines**

**TEL: 012 395 0539**

**Email:** [Buhle.mbongo@health.gov.za](mailto:Buhle.mbongo@health.gov.za)

Dear Ms Mbongo

**Re: RFQ S21RFQ162 – PROTAMINE Inj 10mg/ml 5ml VIALS**

- |                                  |                                   |
|----------------------------------|-----------------------------------|
| • <b>Quantity:</b>               | 10,500 vials                      |
| • <b>Delivery Time (weeks)</b>   | 8-10 weeks after approval         |
| • <b>Price (VAT incl) / vial</b> | R32.81                            |
| • <b>Generic Name:</b>           | Protamine 10mg/ml Injection 5ml   |
| • <b>Trade/Brand Name:</b>       | <b>Protamine Sulphate 10mg/ml</b> |
| • <b>Packaging:</b>              | 5ml packed in 1's                 |
| • <b>Specifications:</b>         | 10mg/ ml Injection                |
| • <b>Shelf-life:</b>             | 36 months                         |
| • <b>Package Insert:</b>         | Attached                          |
| • <b>Manufacturer:</b>           | Kwality Pharmaceuticals           |
| • <b>Country of Origin:</b>      | India                             |

Please note that the immediate availability of the product is under the condition that the manufacturer receives the notice of our order as soon as possible.

We are looking forward to your positive response and please do not hesitate to make contact should you have any further requirements.

Regards

pp

**T Burger**  
**Managing Director**

MC Pharma (Pty) Ltd.  
62 Constantia Avenue,  
Mnandi, Centurion, 0157  
Tel: +27 (0)12 668-3019  
[www.mcpharma.co.za](http://www.mcpharma.co.za)



19 October 2025

## QUOTATION # 20251019P 1

**TO: The National Department of Health**

**TEL: 012 395 0539**

**Email: [Buhle.mbongo@health.gov.za](mailto:Buhle.mbongo@health.gov.za)**

**CONTACT PERSON / PATIENT: Buhle Mbongo**

**NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS**

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE(Single) EXCL	PRICE (Single) INCL
PRO001	Protamine 10mg/ml 5ml vial	1's	10,500	R28,53	R32,81
	<b>TOTAL (ZAR)</b>		<b>Total Quantity</b>	<b>R299,565.00</b>	<b>R344,505.00</b>

Valid for 180 days

Employee signature/s: \_\_\_\_\_

Date: 18 October 2025

Approved by: T Burger





# 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

## 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	S21RFQ162
QUOTE ENQUIRY DATE	08/10/2025	QUOTE CLOSING DATE	19/10/2025	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)				

### REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo		
EMAIL ADDRESS	<a href="mailto:Buhle.Mbongo@health.gov.za">Buhle.Mbongo@health.gov.za</a>		
PHONE No.	012 395 9539	FAX No.	N/A

### PRODUCT INFORMATION


DESCRIPTION PER MPC	PROTAMINE 10MG/ML INJECTION 5ML		
TRADE DESCRIPTION			
UNIT OF MEASURE	1 vial	PACK or BOX (SIZE/ QUANTITY)	1 vial
QUANTITY REQUIRED	10 500 vials/ampoules		

### TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

#### SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	MC Pharma (Pty) Ltd		
SUPPLIER NUMBER	MAAA0714828		
SECURITY CODE			
SUPPLIER CODE (NDoH)			
CONTACT PERSON 1	NAME	T Burger	
	PHONE		FAX
	MOBILE	082 457 7894	
	E-MAIL	<a href="mailto:Tracy.Burger@mcpharma.co.za">Tracy.Burger@mcpharma.co.za</a>	
CONTACT PERSON 2	NAME	J Castle	
	PHONE		



	MOBILE	072 926 8778	
	E-MAIL	Junita.Castle@mcpharma.co.za	
<b><u>QUOTE DETAILS</u></b>			
PRICE PER VIAL (INCL. VAT)	<b>R32.81</b>	TOTAL PRICE (INCL. DELIVERY & VAT)	<b>R344,505.00</b>
*STOCK'S EXPIRY DATE(SHELF-LIFE)			
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS	56-60 days after PO confirmation		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD			
NORMAL LEAD/DELIVERY TIME			
<b><u>DEVIATION TO SPECIFICATION</u></b>			
<b>COMMENTS:</b>			
<b><u>DECLARATION BY SUPPLIER</u></b>			
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	T Burger		
CAPACITY	Managing Director		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)	 pp		
DATE	18 October 2025		
Please submit quotations to <a href="mailto:Section21Quotes@health.gov.za">Section21Quotes@health.gov.za</a>			

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

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Central Supplier Database Summary Report (CSD), updated for the current month
- 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 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 with 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 form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (in cases of a bOPV RFQ).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a 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 required documentation shall not be considered.
- Any submission with blurry required 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.**

***SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION (ON AN OFFICIAL COMPANY LETTERHEAD)***

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150 x 200 mm Front back

# Protamine Sulfate

## Injection USP

10 mg/ml

**NAME OF THE MEDICINAL PRODUCT**  
Protamine Sulfate Injection USP 10mg/ml

**QUALITATIVE AND QUANTITATIVE COMPOSITION**  
Each ml contains :  
Protamine Sulfate USP 10 mg  
Sodium Chloride USP 9 mg  
Water for Injection USP q.s.

**PHARMACEUTICAL FORM**  
Solution for injection  
A clear, colourless solution.

**PHARMACODYNAMIC PROPERTIES**  
Although protamine is a potent antidote for heparin, its precise mechanism of action is unknown. However, when the strongly basic protamine combines with the strongly acid heparin, a stable salt is formed lacking in anticoagulant activity. 1mg of protamine sulfate neutralises between 80 and 120 units of heparin. However, methods of standardisation and the use of heparin from different sources (mucosal, lung) may produce different responses to protamine.

**PHARMACOKINETIC PROPERTIES**  
The onset of action of protamine occurs within five minutes following intravenous administration. The fate of the protamine-heparin complex is unknown, but it may be partially degraded, thus freeing heparin.

**THERAPEUTIC INDICATIONS**  
Protamine sulfate is used to counteract the anticoagulant effect of heparin: before surgery; after renal dialysis; after open-heart surgery; if excessive bleeding occurs and when an overdose has inadvertently been given.

**POSODOGY AND METHOD OF ADMINISTRATION**  
**Adults:**  
Protamine should be administered by slow intravenous injection over a period of about 10 minutes. No more than 50mg of protamine sulfate should be given in any one dose.  
The dose is dependent on the amount and type of heparin to be neutralised, its route of administration and the time elapsed since it was last given, since heparin is continuously being excreted. Ideally, the dose required to neutralise the action of heparin should be guided by blood coagulation studies or calculated from a protamine neutralisation test.  
In gross excess, protamine itself acts as an anticoagulant.  
Neutralisation of unfractionated (UF) heparins:  
1mg of protamine sulfate will usually neutralise at least 100 international units of mucous heparin or 80 units of lung heparin. The dose of protamine sulfate should be reduced if more than 15 minutes have elapsed since intravenous injection.  
For example, if 30-60 minutes have elapsed since heparin was injected intravenously, 0.5-0.75mg protamine sulfate per 100 units of mucous heparin is recommended. If two hours or more have elapsed, 0.25-0.375mg per 100 units of mucous heparin should be administered.  
If the patient is receiving an intravenous infusion of heparin, the infusion should be stopped and 25-50mg of protamine sulfate given by slow intravenous injection.  
If heparin was administered subcutaneously, 1mg protamine sulfate should be given per 100 units of mucous heparin - 25-50mg by slow intravenous injection and the balance by intravenous infusion over 8-16 hours.  
In the reversal of UF heparin following cardiopulmonary bypass, either a standard dose of protamine may be given, as above, or the dose may be titrated according to the activated clotting time.  
Patients should be carefully monitored using either the activated partial thromboplastin time or the activated clotting time, carried out 5-15 minutes after protamine sulfate administration. Further doses may be needed because protamine is cleared from the blood more rapidly than heparin.  
Neutralisation of low molecular weight (LMW) heparins:  
A dose of 1mg per 100 units is usually recommended but the manufacturer's own guidelines should be consulted.  
The anti-Xa activity of LMW heparins may not be completely reversible with protamine sulfate and may persist for up to 24 hours after administration.  
The longer half-life of LMW heparins (approximately twice that of UF heparin) should also be borne in mind when estimating the dose of protamine sulfate required in relation to the time which has elapsed since the last heparin dose.  
Theoretically, the dose of protamine sulfate should be halved when one half-life has elapsed since the

last LMW heparin dose. Intermittent injections or continuous infusion of protamine sulfate have been recommended for the neutralisation of LMW heparin following subcutaneous administration, as the drug may be continuing absorption from the subcutaneous depot.  
Patients should be carefully monitored. Further doses may be needed because protamine is cleared from the blood more rapidly than heparin, especially low molecular weight heparin.  
**Elderly:**  
There is no current evidence for alteration of the recommended dose.  
**Children:**  
Safety and efficacy in children have not been established. Not recommended.

**CONTRAINDICATIONS:**  
Patients who have shown previous intolerance to the drug.

**SPECIAL WARNINGS AND PRECAUTIONS FOR USE**  
Too rapid administration of protamine sulfate may cause severe hypotension and anaphylactoid reactions. Facilities for resuscitation and treatment of shock should be available.  
Protamine sulfate is not suitable for reversing the effects of oral anticoagulants. Caution should be observed when administering protamine sulfate to patients who may be at increased risk of allergic reaction to protamine. These patients include those who have previously undergone procedures such as coronary angioplasty or cardio-pulmonary by-pass which may include use of protamine, diabetics who have been treated with protamine insulin, patients allergic to fish and men who have had vasectomy or are infertile and may have antibodies to protamine.  
Patients undergoing prolonged procedures involving repeated doses of protamine should be subjected to careful monitoring of clotting parameters. A rebound bleeding effect may occur up to 18 hours post-operatively which responds to further doses of protamine.

**FERTILITY, PREGNANCY AND LACTATION**  
As with most drugs, to be used only if clearly indicated in pregnancy and with caution during lactation.

**UNDESIRABLE EFFECTS**  
Blood and lymphatic system disorders: anticoagulant effect (when used at doses in excess of those required to neutralise the anticoagulant effect of heparin).  
Immune system disorders: Hypersensitivity reactions, including angioedema anaphylactoid reactions and fatal anaphylaxis, have been reported.  
Cardiac disorders: bradycardia  
Vascular disorders: sudden fall in blood pressure, pulmonary and systemic hypertension, transitory flushing and a feeling of warmth, severe, acute pulmonary vasoconstriction with cardiovascular collapse  
Respiratory, thoracic and mediastinal disorders: Dyspnoea. There have been rare instances of noncardiogenic pulmonary oedema with prolonged hypotension, with significant morbidity and mortality.  
Gastrointestinal disorders: nausea and vomiting  
Musculoskeletal and connective tissue disorders: back pain  
General disorders and administration site conditions: lassitude  
**Reporting of suspected adverse reactions**  
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

**OVERDOSE**  
Symptoms:- Protamine has weak anticoagulating properties and if given in the absence of heparin, at doses in excess of those required to neutralise the anticoagulant effect of heparin, exerts its own anticoagulant effect.  
Hypotension, bradycardia, dyspnoea nausea, vomiting, lassitude, transitory flushing and/ or sensation of warmth may also occur.  
Treatment:- Includes monitoring of coagulation tests, respiratory ventilation and symptomatic treatment. If bleeding is a problem, fresh frozen plasma or fresh whole blood should be given.

**STORAGE:**  
Store at a temperature not exceeding 30°C. Do not freeze. Discard unused portion.  
Keep out of the reach of children.

**PRESENTATION:**  
5 ml vial enclosed in a plastic tray and each tray packed in a printed carton.  
  
Manufactured by :  
**Kwality Pharmaceuticals Ltd.**  
Nag Kalan, Majitha Road, Amritsar - India

<b>Component : Carton</b>
<b>Dimension : 50 x 30 x 75 mm</b>
<b>Colour : CMYK</b>
<b>ITC Cyber XL 320 GSM - U.V Coating</b>



Batch :  
Mfg. :  
Exp. :

# Protamine Sulfate

**1 vial of 5 ml**

# Protamine Sulfate Injection USP

10 mg/ml

**For IV use only**

**Each ml contains :**  
 Protamine Sulfate USP 10 mg  
 Sodium Chloride USP 9 mg  
 Water for Injection USP q.s.

Each mg of Protamine Sulfate, calculated on the dried basis, neutralizes not less than 100 USP Heparin Units.

**Dosage:**  
As directed by the Physician.

**Storage:**  
Store at a temperature  
not exceeding 30°C.  
Do not freeze.

Read the pack insert carefully before use.

Keep out of the reach  
of children.

Do not use the Injection if it is not clear.

**1 vial of 5 ml**

# Protamine Sulfate Injection USP

10 mg/ml

**For IV use only**

**Discard unused portion**  
Mfg. Lic. No.: 1804-B

Manufactured by :  
**Kwality Pharmaceuticals Ltd.**  
Nag Kalan, Majitha Road,  
Amritsar - INDIA

**Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2022 to Jan/2025**

Check List for Labeling														
Tender List 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
13655/1	English													
Matching all parameters between Box and Label														
Previous specimen artwork : NEW				Designed by : Ramesh kumar				Order Quantity	Party Name		Packing			
Checked by :		Approved by :		Authorized by:		Party Approval		39000 vials	INDOCO		1 vial			
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton :						
								C.B. W.D. L.T.C. Bond						

Do not use the Injection if it is not clear.

**Exp. :**

Tender List 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
13655/1	English													
Matching all parameters between Box and Label														
Previous specimen artwork : NEW				Designed by : Ramesh kumar				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by:		Party Approval		39000 vials		INDOCO		1 vial		
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton :						
								CIB, WIP, LTC, ...						