



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 E van Zyl  
Equity Pharmaceuticals (Pty) Ltd  
100 Sovereign Road  
Route 21 Corporate Park  
Nellmapius Drive  
Irene  
**Pretoria**

Dear Mr van Zyl

#### **Section 21 Extension Authorization for BENZYL PENICILLIN 1MU INJ**

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

- **Benzyl Penicillin 1MU INJ**

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.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

**Section 21 Extension Authorisation re Benzyl Penicillin 1MU INJ 23052024**

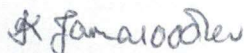
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent over stocking 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 **22 November 2024**.

**Table 1: Provincial estimates vs uptake**

Province	Six Months Estimate	Actual Uptake
Correctional Services	0	0
EC-MT	15 600	19 130
EC-PE	14 000	
FS	2 100	1 150
GP	0	3 870
KZN	8 000	8 000
LP	0	0
MP	17 644	17 650
NC	1 500	1 500
NW	3 900	1 600
SAMHS	0	0
WC	3 000	3 000
<b>Total</b>	<b>65 744</b>	<b>55 900</b>

Yours sincerely



**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**

DATE: 04/11/2024



## Section 21 Response Letter

5/22/2024 2:57 PM

Khadija Jamaloodien

National Department of Health  
Dr AB Xuma Building  
1112 Voortrekker Rd  
Pretoria Townlands 351-JR  
Pretoria  
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

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

Your application dated 5/22/2024 1:47 PM refers

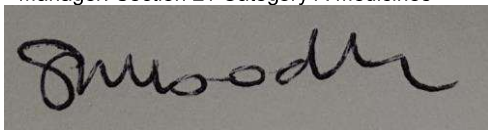
- A. **STATUS: Approved**
- B. **APPLICANT: Khadija Jamaloodien**
- C. **IMPORTING COMPANY: Equity Pharmaceuticals (Pty) Ltd**
- D. **PATIENT/(S):**
- E. **UNREGISTERED MEDICINES:**
  - GENERIC NAME: Benzyl Penicillin**
  - 1MU INJ**
  - TRADE NAME: Benzyl Penicillin**
  - for injection BP 1MU**
- F. **QUANTITY: Benzyl Penicillin 1MU**  
**INJ x 10100 vials**
- G. **LETTER NUMBER: B-27539**

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

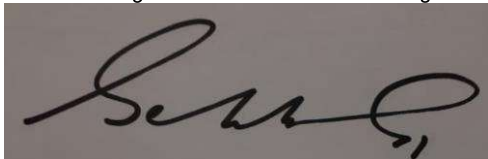
Comments:

Yours faithfully,

Dr S Munbodh  
Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature is cursive and appears to read 'S. Munbodh'.

T Sehloho  
Senior Manager: Clinical Evaluations Management

A rectangular box containing a handwritten signature in black ink. The signature is cursive and appears to read 'T. Sehloho'.



# health

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## 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	S21RFQ129
QUOTE ENQUIRY DATE	10/08/2023	QUOTE CLOSING DATE	21/08/2023	
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	BENZYL PENICILLIN 1MU INJECTION			
TRADE DESCRIPTION	Benzylpenicillin for Injection BP 1MU			
UNIT OF MEASURE	1's	PACK or BOX ( <u>SIZE/ QUANTITY</u> )	1's	
QUANTITY REQUIRED	66 000 VIALS/AMPOULES			

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

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

COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	012 345 1747	FAX	012 345 1412
	MOBILE	072 040 8511		
	E-MAIL	ehrdard@equitypharma.co.za		
CONTACT PERSON 2	NAME	Jaco Schoeman		
	PHONE	012 345 1747		

	MOBILE	076 734 0080	
	E-MAIL	jacos@equitypharma.co.za	
<b><u>QUOTE DETAILS</u></b>			
PRICE PER UNIT (INCL. VAT)	R 4.83	TOTAL PRICE (INCL. DELIVERY & VAT)	R 318 780.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	66 000		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 day		
<b><u>DEVIATION TO SPECIFICATION</u></b>			
<i>COMMENTS:</i>			
<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	Ehrard van Zyl		
CAPACITY	Business Unit Manager: Specialist Medicine		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	21/08/2023		
<b>Please submit quotations to <a href="mailto:Section21Quotes@health.gov.za">Section21Quotes@health.gov.za</a></b>			

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)
- 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 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.
- 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.
- 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.
- 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**

21/08/2023



Equity Pharmaceuticals (Pty) Ltd.  
1997/009942/07

+27 12 345 1747  
+27 12 345 1412  
equity@equitypharma.co.za

www.clinigengroup.com  
www.equitypharma.co.za

## QUOTATION # 20230821

TO: National Department of Health

TEL: 012 395 9539

FAX:

Email: [Section21Quotes@health.gov.za](mailto:Section21Quotes@health.gov.za)

CONTACT PERSON: Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Benzylpenicillin for Injection BP 1MU	1's	1	R 4.20	R 4.83
			66 000	R 277 200.00	R 318 780.00
			66 000	R 277 200.00	R 318 780.00

Valid for 180 days

Employee Signature: 

Date: 21/08/2023

Approved by: Ehrard van Zyl / Carel Bouwer



21/08/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: [Buhle.Mbongo@health.gov.za](mailto:Buhle.Mbongo@health.gov.za)

Attention: Ms Buhle Mbongo

Equity Pharmaceuticals (Pty) Ltd.  
1997/009942/07

+27 12 345 1747

+27 12 345 1412

[equity@equitypharma.co.za](mailto:equity@equitypharma.co.za)

[www.clinigengroup.com](http://www.clinigengroup.com)  
[www.equitypharma.co.za](http://www.equitypharma.co.za)

Dear Ms Mbongo

**Re: Request for quotation – Benzyl Penicillin 1MU – Section 21 Supply**

Trust you are well. Please find below our quotation for *Benzylpenicillin for Injection BP 1MU* supplied under section 21 terms.

- |                          |   |
|--------------------------|---|
| • Quantity:              | <b>66 000 vials</b>                                     |
| • Delivery Time (Weeks): | <b>8 Weeks after approval</b>                           |
| • Price (Vat Inclusive): | <b>R 4.83 per vial</b>                                  |
| • Generic Name:          | <b>Benzyl Penicillin for Injection BP 1MU</b>           |
| • Trade Name:            | <b>Benzylpenicillin for Injection BP 1MU</b>            |
| • Packaging:             | <b>1 vial</b>   |
| • Specifications:        | <b>1 Million Units</b>                                  |
| • Shelf Life:            | <b>24 months</b>  |
| • Package Insert:        | <b>Attached</b>   |
| • Manufacturer:          | <b>Karnataka Antibiotics &amp; Pharmaceuticals Ltd.</b> |
| • Country of Origin:     | <b>India</b>  |

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards



Ehrard van Zyl

# Benzylpenicillin for Injection BP 1.0 MU & 5.0 MU - KAPL Export Pack Insert

Open Length 340 (L) x 240(H) mm  
57 GSM White Print Paper, Colour Black

**Immune System Disorders**

*Very Common* (>10%)

Patients undergoing treatment for syphilis or neurosyphilis with Benzylpenicillin may develop a Jarisch-Herxheimer reaction.

*Common* (1-10%)

Hypersensitivity to penicillin in the form of rashes (all types), fever, and serum sickness may occur (1-10% treated patients). These may be treated with antihistamine drugs.

*Rare* (0.01%-0.1%)

More rarely, anaphylactic reactions have been reported (<0.05% treated patients).

**Nervous System Disorders**

*Rare* (0.01%-0.1%)

Central nervous system toxicity, including convulsions, has been reported with massive doses over 60 g per day and in patients with severe renal impairment.

**Renal and Urinary Disorders**

*Rare* (0.01%-0.1%)

Interstitial nephritis has been reported after intravenous Benzylpenicillin sodium BP at doses of more than 12 g per day.

**Symptoms and Treatment of Overdose**

Symptoms of overdose includes convulsion and neurological adverse reactions. In case of overdose, discontinue medication, treat symptomatically and institute supportive measures as required. In patients with renal function impairment, ampicillin-class antibiotics can be removed by haemodialysis but not by peritoneal dialysis.

**Presentation**

One folded paper box contains 10 vials or 50 vials.

**Storage Condition**

Store below 30°C.

**Shelf Life**

Unopened vials: 36 months from the date of manufacture, if kept as recommended.  
Reconstituted solution: Freshly prepared solutions should be used immediately.

**Manufactured by:**

**KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED**  
Plot No. 14, II Phase, Peenya Industrial Area, Bengaluru, 560 058, INDIA.  
Tel: 091 (080) 23372123  
Fax: 091 (080) 23371350

**Date of revision of package insert**

April 2022

## Benzylpenicillin

**Product Name**  
BENZYLPENICILLIN FOR INJECTION BP 1.0 MU  
BENZYLPENICILLIN FOR INJECTION BP 5.0 MU

**Product Description**

A white crystalline powder in glass vials. Pale yellow solution

**Composition**

BENZYLPENICILLIN FOR INJECTION BP 1MU  
Each vial contains Benzylpenicillin Sodium BP 600 mg.

BENZYLPENICILLIN FOR INJECTION BP 5MU  
Each vial contains Benzylpenicillin Sodium BP 3 g.

**Pharmacodynamics**

**General Properties:**

Benzylpenicillin sodium BP is a beta-lactam antibiotic. It is

**Breakpoints:**

The tentative breakpoints (British Society for Antimicrobial

Organism	Susceptibility %
Streptococcus pneumoniae	0.06
Neisseria gonorrhoeae	0.06
Neisseria meningitidis	0.06
Haemolytic streptococci	0.12
Staphylococci	0.12
Moraxella catarrhalis	0.12
Haemophilus influenza	0.12
Rapidly growing anaerobes	1.0

**Susceptibility:**

The prevalence of resistance may vary geographically and treating severe infections. The following table gives Benzylpenicillin sodium BP or not.

Susceptible and intermediately susceptible microorganism	Microorganism
Aerobic Gram-positive microorganism	Bacillus anthracis Corynebacterium diphtheriae Haemolytic streptococci (pyrogenes) Listeria monocytogenes Streptococcus pneumoniae Streptococcus viridans
Aerobic Gram-negative microorganisms	Neisseria gonorrhoeae Neisseria meningitidis Pasteurella multocida
Anaerobic microorganisms	Actinomyces israelii Fusobacterium nucleatum Fusobacterium necrophorum Gram-positive sporing tetani and Clostridium perfringens Gram-positive cocci (infecting wounds)
Other microorganism	Borrelia burgdorferi Capnocytophaga canimorsus Leptospirae

**Other Information:**

**Known Resistance Mechanisms and Cross-resistance**

Penicillin resistance can be mediated by alteration of penicillin binding proteins or development of beta-lactamases.

Resistance to penicillin may be associated with cross-resistance to a variety of other beta lactam antibiotics either due to a shared target site that is altered, or due to a beta-lactamase with a broad range of substrate molecules. In addition to this, cross resistance to unrelated antibiotics can develop due to more than one resistance gene being present on a mobile section of DNA (e.g. plasmid, transposon etc) resulting in two or more resistance mechanisms being transferred to a new organism at the same time.

**Pharmacokinetics**

Benzylpenicillin sodium BP rapidly appears in the blood following intramuscular injection of water-soluble salts and maximum concentrations are usually reached in 1.5-30 minutes. Peak plasma concentrations of about 12 mcg/ml have been reported after doses of 600 mg with therapeutic plasma concentrations for most susceptible organisms detectable for about 5 hours. Approximately 60% of the dose injected is reversibly bound to plasma protein.

In adults with normal renal function the plasma half-life is about 30 minutes. Most of the dose (60-90%) undergoes renal elimination, 10% by glomerular filtration and 90% by tubular secretion. Tubular secretion is inhibited by probenecid, which is sometimes given to increase plasma penicillin concentrations. Biliary elimination of Benzylpenicillin sodium BP accounts for only a minor fraction of the dose.

**Indication**

Benzylpenicillin is indicated for most wound infections, pyogenic infections of the skin, soft tissue infections and infections of the respiratory tract. It is also indicated for the following infections caused by penicillin-sensitive microorganisms:

Generalised infections and septicaemia from susceptible bacteria.

Acute and chronic osteomyelitis, sub-acute bacterial endocarditis and meningitis caused by susceptible organisms.

Tetanus, actinomycosis, anthrax, rat-bite fever, listeriosis and severe Lyme disease.

Complications secondary to gonorrhoea and syphilis (e.g. gonococcal arthritis or endocarditis, congenital syphilis and neurosyphilis).

Diphtheria, brain abscesses and pasteurellosis.

Consideration should be given to official local guidance (e.g. national recommendations) on the appropriate use of antibacterial agents.

Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

**Recommended Dosage**

**Route of administration:**

The following dosages apply to both intramuscular and intravenous injection.

Alternate sites should be used for repeated injections.

**Preparation of solution:**

Reconstituted solutions of Benzylpenicillin sodium BP are intended for immediate administration.

600mg vial

Dissolve the contents in 2ml or more of Sterilised Water for Injections immediately before use.

3g vial

Dissolve the contents in 10ml or more of Sterilised Water for Injections immediately before use.

**Dosage and administration:**

*Adults*

600 to 3,600 mg (1 to 6 mega units) daily, divided into 4 to 6 doses, depending on the indication. Higher doses (up to 14.4 g/day (24 mega units) in divided doses) may be given in serious infections such as adult meningitis by the intravenous route.

In bacterial endocarditis, 7.2 to 12 g (12 to 20 mega units) or more may be given daily in divided doses by the intravenous route, often by infusion.

High doses should be administered by intravenous injection or infusion, with intravenous doses in excess of 1.2g (2 mega units) being given slowly, taking at least one minute for each 300 mg (0.5 mega unit) to avoid high levels causing irritation of the central nervous system and/or electrolyte imbalance.

High dosage of Benzylpenicillin sodium BP may result in hypernatraemia and hypokalaemia unless the sodium content is taken into account.

*Children aged 1 month to 12 years*

100 mg/kg/day in 4 divided doses; not exceeding 4 g/day.

*Infants 1-4 weeks*

75 mg/kg/day in 3 divided doses.

*Newborn Infants*

50 mg/kg/day in 2 divided doses.

Creatinine clearance (mL per minute)	Dose (g)
125	1.2
or	or
1.8	1.8
60	1.2
40	0.9
20	0.6
10	0.6
Nil	0.3
	or
	0.6

# Benzylopicillin for Injection BP 600 mg 1.0 MIU Vial Sticker label

65 (L) x 18 (H) mm

4 colour (Cyan, Mazenta, Yellow, Black)  
Ref. specification No.FD/VL/3LP0913/00

← 65 mm →

← 18 mm →



300 % Enlarged size

Each vial contains:  
**Benzylpenicillin Sodium BP  
equivalent to  
Benzylpenicillin 600 mg**

Please refer to package insert for  
direction of reconstitution solution.


FOR IM / IV INJECTION

**Benzylpenicillin  
for Injection BP 600 mg  
(1 MIU)**

Manufactured by:  
**KARNATAKA ANTIBIOTICS &  
PHARMACEUTICALS LIMITED**  
Plot No. 14, II Phase, Peenya Industrial  
Area, Bengaluru 560 058, INDIA.

# Benzylopeni

Ref

	<p>0 89 02372 00062 1</p> 	<p><b>10 VIALS</b></p> <p><b>Benzylopicillin For Injection BP 600 mg (1 MIU)</b></p>	<p>Manufactured by: <b>KARNATAKA ANTIBIOTICS &amp; PHARMACEUTICALS LIMITED</b> Plot No. 14, II Phase, Peenya Industrial Area, Bengaluru 560 058, INDIA.</p>
		<p><b>10 VIALS</b></p> <p><b>Benzylopicillin For Injection BP 600 mg (1 MIU)</b></p>	<p>Manufactured by: <b>KARNATAKA ANTIBIOTICS &amp; PHARMACEUTICALS LIMITED</b> Plot No. 14, II Phase, Peenya Industrial Area, Bengaluru 560 058, INDIA.</p>
		<p>3CT0066P/001/0422</p>	<p>Each vial contains: <b>Benzylopicillin Sodium BP</b> equivalent to <b>Benzylopicillin 600 mg</b></p> <p>Please refer to package insert for direction of reconstitution solution.</p> <p><b>FOR IM / IV INJECTION</b></p> <p>Not to be Used in patients with known hypersensitivity to Penicillin</p> <p>Store below 30°C.</p>

45 mm

125 mm

50 mm