



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 Authorization for PHENOBARBITONE 200MG/ML INJECTION 1ML**

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

- **Phenobarbitone 200mg/mL Injection 1mL**

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.
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.

**Section 21 Authorisation re Phenobarbitone 200mg INJ 1mL 14122023**

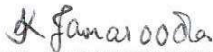
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent over stocking once the contracted supplier gets back 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 **13 June 2024**.

**Table 1: Provincial estimates**

<b>Provinces</b>	<b>Six Months Estimated Quantity</b>
DCS	0
EC -MT	180
EC-PE	0
FS	300
GP	1500
KZN	3500
LP	300
MP	2700
NC	900
NW	1200
SAMHS	0
WC	4000
<b>Total</b>	<b>14580</b>

Yours sincerely



**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 14/12/2023**



## Section 21 Response Letter

12/13/2023 10:43 AM

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 12/12/2023 2:26 PM refers

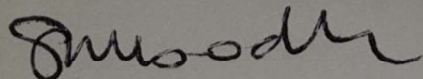
- A. STATUS: Approved**
- B. APPLICANT: Khadija Jamaloodien**
- C. IMPORTING COMPANY: Equity Pharmaceuticals (Pty) Ltd**
- D. PATIENT/(S):**
- E. UNREGISTERED MEDICINES:**
  - GENERIC NAME: Phenobarbital Sodium**
  - TRADE NAME: Phenobarbital Sodium Injection USP**
- F. QUANTITY: Phenobarbital Sodium 200mg/mL Injection 1mL x 15 000 Ampoules**
- G. LETTER NUMBER: B-23234**

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

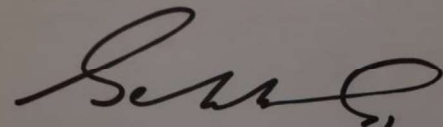
**Comments:**

Yours faithfully,

Dr S Munbodh  
Manager: Section 21 Category A Medicines

A handwritten signature in black ink on a grey background, appearing to read 'S Munbodh'.


T Sehloho  
Senior Manager: Clinical Evaluations Management

A handwritten signature in black ink on a grey background, appearing to read 'T Sehloho'.



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

<b>REQUEST FOR QUOTATION FORM</b>				
<ul style="list-style-type: none"> <li><b>Instruction to complete this Request for Quotation (RFQ)</b> 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.</li> <li><b>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.</b></li> </ul>				
<b>ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED</b>				
REFERENCE NUMBER:	NORMAL	SECTION 21	X	S21RFQ134
QUOTE ENQUIRY DATE	07/11/2023	QUOTE CLOSING DATE	16/11/2023	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)				
<b>REQUESTING INSTITUTION CONTACT DETAILS</b>				
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	
<b>PRODUCT INFORMATION</b>				
DESCRIPTION PER MPC	Phenobarbitone 200mg Injection			
TRADE DESCRIPTION	Phenobarbital Sodium Injection USP 200mg/ml			
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	10's	
QUANTITY REQUIRED	15 000 Amps (1 500 packs)			
<b>TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER</b>				
<b>SUPPLIER CONTACT DETAILS (as per CSD)</b>				
COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA0007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	0123451747	FAX	0123451412
	MOBILE	0720408511		
	E-MAIL	ehrd@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 151.80	TOTAL PRICE (INCL. DELIVERY & VAT)	R 227 700.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS	15 000 amps (1 500 packs)		
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
<b><u>DEVIATION TO SPECIFICATION</u></b>			
<i>COMMENTS: Price quoted is per pack of 10 amps (R 151.80) i.e. R 15.18 incl. vat per amp.</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	16/11/2023		
<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 be submitted in two decimals. Failure to do so will result in NDoH determining their own final price.
- 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.
- Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.
- **Only** quotations should be sent to [Section21Quotes@health.gov.za](mailto:Section21Quotes@health.gov.za). All other queries to be directed to [Buhle.Mbongo@health.gov.za](mailto:Buhle.Mbongo@health.gov.za)
- Any quotation sent to [Buhle.Mbongo@health.gov.za](mailto:Buhle.Mbongo@health.gov.za) will not be considered.

Please **SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD**

16/11/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: [Section21Quotes@health.gov.za](mailto:Section21Quotes@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 – Phenobarbitone 200mg/ml – Section 21 Supply**

Trust you are well. Please find below our quotation for *Phenobarbitone 200mg/ml injections* supplied under section 21 terms.

- Quantity: **1 500 packs (15 000 amps)**
- Delivery Time (Weeks): **7 Weeks**
- Price (Vat Inclusive): **R 151.80 incl. vat per pack of 10 amps**
- Generic Name: **Phenobarbitone 200mg/ml**
- Trade Name: **Phenobarbital Sodium Injection USP 200mg/ml**
- Packaging: **10 x 1ml amps**
- Specifications: **200mg/ml**
- Shelf Life: **24 months**
- Package Insert: **Attached**
- Manufacturer: **Kwality**
- Country of Origin: **India**

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





16/11/2023

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

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

## QUOTATION # 20231116

TO: National Department of Health

TEL: 012 395 9539

FAX:

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

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

CONTACT PERSON / PATIENT: Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Phenobarbital Sodium Injection USP 200mg/ml	10 x 1ml	1	R 132.00	R 151.80
			1 500	R 198 000.00	R 227 700.00
			1 500	R 198 000.00	R 227 700.00

Valid for 180 days

Employee Signature: \_\_\_\_\_

Date: 16/11/2023

Approved by: Ehrard van Zyl / Carel Bouwer

100x200mm

# PHENOBARBITAL SODIUM INJECTION USP

**200 mg/ml**

## COMPOSITION:

Each ml contains:  
Phenobarbital Sodium USP 200 mg  
Alcohol USP 10% v/v  
Propylene Glycol USP q.s.  
(as solvent)

## CATEGORY:

Barbiturate.

## GENERAL INFORMATION:

Phenobarbital & Amylobarbitone belong to the group Barbiturates of CNS depressants. They are hypnotic drugs.

## MOA:

Barbiturates are CNS depressants. They also augment inhibitory effects of GABA. Effects range from sedation and in high doses cause anaesthesia.

## INDICATIONS:

Intractable insomnia, eclampsia, spastic excitatory states. Generalised tonic clonic seizures, febrile convulsion, temporal lobe epilepsy, cortical focal seizures, status epilepticus.

## DOSAGE AND ADMINISTRATION:

Adults: 30-210mg daily in divided doses.

Children: Phenobarbitone:

- 1) For sedation: PO, I.M.: 2-3 mg/kg/24hour divided every 8-12 hour.
- 2) For sleep: PO, I.M.: 2-3 mg/kg/dose, repeat sos after 12-24 hour.
- 3) Long term anticonvulsant Rx: Start with 1.5mg/kg/24 hours, divided every 12 hours, increase according to tolerance and therapeutic effect to 4-6mg/kg/24 hour divided every 12 hours or as a single daily dose, preferably at bed time.
- 4) In status epilepticus, I.V.: 10-20mg/kg loading dose by slow I.V. injection followed after interval of 5 minutes by 5-10mg/kg/dose to be repeated at 20 minute intervals until seizures are controlled or a total dose of 40mg/kg is reached.

## CONTRAINDICATIONS:

Barbiturates are contraindicated in acute intermittent porphyria, uncontrolled pain and debilitated individuals and in cases of alcohol and drug abuse. Hyperkinetic children.

## ADVERSE EFFECTS:

Main side effect is sedation (which disappears after a few weeks due to development of tolerance). In young and elderly it causes confusion and paradoxical excitement or agitation. Irritability and hyperactivity in children may be seen. Megaloblastic anaemia, osteomalacia and skin rashes may occur. Rarely hepatitis and agranulocytosis may occur. The toxicity is manifested by hypotension, ataxia, dizziness, respiratory depression, coma & death.

## SPECIAL PRECAUTIONS:

Chronic use of barbiturates may result in intolerance and drug dependence. Barbiturates cause decreased efficacy of other drugs because of hepatic microsomal enzyme induction in liver and accelerated metabolism of oral anticoagulants, oral contraceptives and phenytoin. Respiratory insufficiency.

## INTERACTIONS:

Alcohol & other CNS Depressants (other sedatives, hypnotics, anesthetics, antihistamines, tranquilizers, phenothiazines): Additive CNS depression.

Valproic acid: Increases efficacy of barbiturates. Half life of valproic acid may be decreased.

Chloramphenicol: Efficacy of barbiturates increased. Barbiturates may decrease efficacy of chloramphenicol.

MAOIs: Effects of barbiturates prolonged.

Efficacy of the following drugs decreased by barbiturates: Oral anticoagulants, digitoxin, TCAs, corticosteroids, doxycycline, oral contraceptives and estrogens, acetaminophen, beta-blockers, quinidine, rifampicin, theophylline and metronidazole.

Phenytoin: Effect on phenytoin metabolism is unpredictable.

Furosemide: May produce or aggravate orthostatic hypotension.

Griseofulvin: Interferes with absorption of oral griseofulvin leading to decreased blood levels.

## STORAGE:

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

Keep out of the reach of children.


## PRESENTATION:

10 ampoules of 1ml are in a plastic tray and each tray packed in a printed box.

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

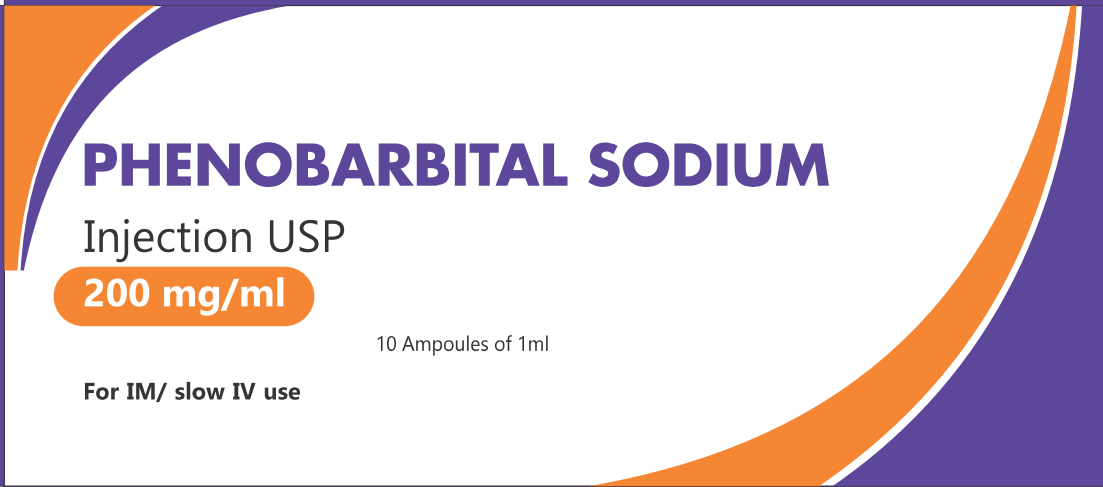


<b>Component :</b> Carton
<b>Dimension :</b> 149 x 13 x 65 mm
<b>Colour :</b> CMYK
<b>GSM :</b> 320 gsm ITC CYBER XL
<b>Varnish / coating:</b> U.V. coating

<p><b>Composition :</b> Each ml contains: Phenobarbital Sodium USP    200 mg Alcohol USP                        10% v/v Propylene Glycol USP            q.s. (as solvent)</p> <p><b>Dosage:</b> As directed by the physician</p> <p><b>Storage:</b> Store between temperature 8° to 25°C. Protect from light.</p> <p><b>Warning:</b> <b>Do not use if precipitate appears.</b></p>	<p>Read enclosed leaflet carefully before use.</p> <p>Keep out of the reach of children.</p> <p>Mfg. Lic. No. : 1804-B</p> <p>Manufactured by: <b>Kwality Pharmaceuticals Ltd.</b> Nag Kalan, Majitha Road, Amritsar-India</p>		<p>Batch No. : Mfg. Date : Exp. Date :</p>
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**PHENOBARBITAL SODIUM**  
Injection USP
**(200 mg/ml)**

**PHENOBARBITAL SODIUM**  
Injection USP  
**(200 mg/ml)**



**PHENOBARBITAL SODIUM**  
Injection USP  
**200 mg/ml**  
10 Ampoules of 1ml  
For IM/ slow IV use

**PHENOBARBITAL SODIUM**  
Injection USP
**(200 mg/ml)**

**Expiry Date is 36 months from the Mfg. Date. For eg. 05/2019 to 04/2022**

Check List for Labeling											Formulation No.: 03421			
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
<b>11508/1</b>	English													
Matching all parameters between Box and Label														
Matching the parameter with label of leader brand														
Previous specimen artwork : NEW				Designed by : CHINU RAICHAND				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by :		Party Approval		15000 amps		Equity				
Production Incharge	QC Incharge	Q.A.		M.D.				Card Board used for carton :						
								<input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl						