



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 GLYCERYL TRINITRATE 1MG/ML INJ 10ML

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

- **Glyceryl Trinitrate 1mg/mL Injection 10mL**

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 Glyceryl Trinitrate 1mg/mL INJ 10mL 09022026-2**

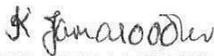
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, 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 **05 August 2026**.

**Table 1: Provincial usage data**

<b>Province</b>	<b>Six Months Estimate</b>	<b>Actual Uptake</b>
<b>Correctional Services</b>	0	0
<b>EC-MT</b>	120	410
<b>EC-PE</b>	0	
<b>FS</b>	1260	40
<b>GP</b>	6000	6 750
<b>KZN</b>	5000	5000
<b>LP</b>	0	0
<b>MP</b>	110	220
<b>NC</b>	600	900
<b>NW</b>	332	400
<b>SAMHS</b>	0	0
<b>WC</b>	7000	2 970
<b>Total</b>	<b>20 422</b>	<b>16 690</b>

Yours sincerely



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

**DATE: 12/12/2026**

## Section 21 Outcome Letter

2026-02-05

Ms Buhle Mbongo

National Department Of Health

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 **2026-02-04** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 96**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Nitroswiss 1 mg/L**
- G. QUANTITY: 3840 Packs (1 )**

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**H. LETTER NUMBER: S2100021524**

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

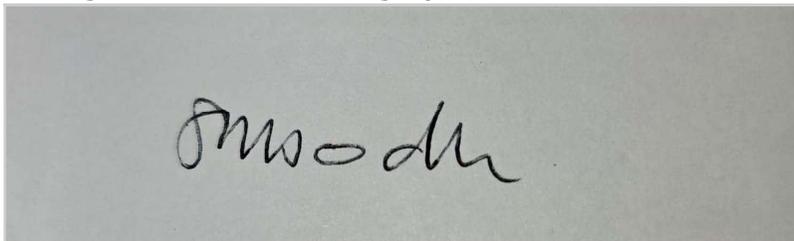
A progress report must be submitted once treatment is completed or on a reauthorization request

**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

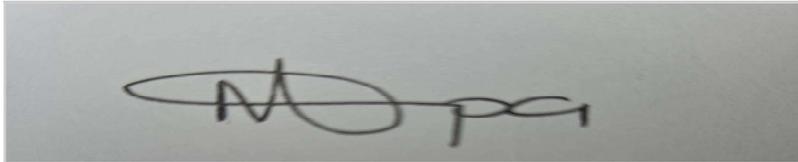
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S2100021524



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





24/02/2026

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

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

## QUOTATION # 20260226

National Department of Health

Tel: 012 395 9539

Fax:

Email: Section21Quotes@health.gov.za

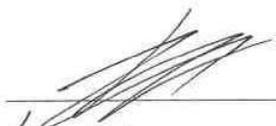
www.clinigengroup.com  
www.equitypharma.co.za

**CONTACT PERSON: Buhle Mbongo**

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
Nitroswiss (Nitroglycerine) Injection USP 1mg/1ml	1 x 10ml	1	R 30.85	R 35.47
		<b>3 810</b>	<b>R 117 538.50</b>	<b>R 135 140.70</b>
			<b>R 117 538.50</b>	<b>R 135 140.70</b>

Valid for 180 days

Employee Signature: 

Date: 24/02/2026

Approved by: Ehrard van Zyl



Prescription Only Medicine

**NITROSWISS**  
Nitroglycerin Injection USP 1 mg/ml, 10 ml  
(Glyceryl Trinitrate)  
For IV Infusion only

**Composition :**  
Each ml contains :  
Diluted Nitroglycerin USP (10%)  
Equivalent to Nitroglycerin... 1 mg  
Ethanol BP .....30 % v/v  
Propylene Glycol BP .....30 % v/v  
Water for Injections BP.....q.s.

**Dosage:** As directed by the physician.  
Not for direct IV Injection, Must be diluted before use.  
Discard unused portion

**Storage :**  
Store below 30°C, Protect from light.  
**KEEP OUT OF REACH OF CHILDREN.**

Batch No. :  
Mfg. Date :  
Exp. Date :

Manufactured by :  
**SWISS PARENTERALS LTD.**  
808, 809 & 810, Kerala Industrial Estate,  
GIDC, Nr. Bavla, Dist.: Ahmedabad-382220,  
Gujarat, INDIA.

Actual size

Prescription Only Medicine

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Enlarge size

-  PANTONE 1525 C
-  PANTONE 721 C
-  BLACK

