health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 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 Extension Authorization for VINCRISTINE 1MG/ML INJ 2ML

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

- **Vincristine 1mg/mL Injection 2mL**

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.
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 21authorisation 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 the use of the product in the public sector with estimated usage quantities for a period of six months. The authorization is expected to expire on **03 March 2026**.

Table 1: Provincial usage data

Province	Six Months Estimate	Actual Uptake
DCS	0	0
EC-MT	120	300
EC-PE	1200	
FS	500	300
GP	1800	600
KZN	1800	2100
LP	0	0
MP	0	190
NC	240	300
NW	0	0
SAMHS	18	0
WC	2400	2100
Total	**8 078**	**5 890**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 5/9/2025

S2100011073

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

Section 21 Outcome Letter

2025-09-04

Ms Buhle Mbongo

1112 Voortrekker Street

Springbok

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 **2025-09-02** 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: 1100

E. UNREGISTERED MEDICINES: GENERIC NAME: No Data

F. TRADE NAME: Vincristine Sulphate for Injection 1 mg/mL

G. QUANTITY: 2200 Packs (1)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100011073

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

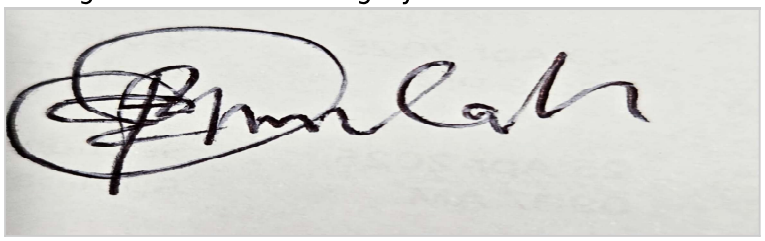
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Ebenezer Minlah

Manager: Section 21 Category A Medicines



Dr Shyamli Munbodh

Final Approver

S2100011073

SAHPRA
South African
Health Products
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SAHPRA Head Office
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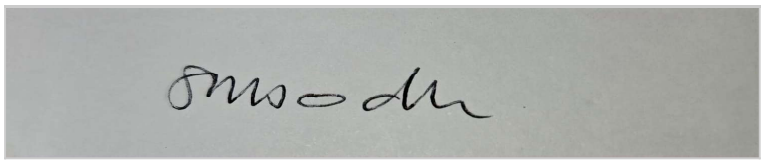


MC Pharma (Pty) Ltd.
62 Constantia Avenue,
Mnandi, Centurion, 0157
Tel: +27 (0)12 668-3019
www.mcpharma.co.za

19 February 2025

TO: The National Department of Health

Directorate: Affordable Medicines

TEL: 012 395 0539
Email: Buhle.mbongo@health.gov.za

Dear Ms Mbongo

Re: RFQ S21RFQ148 – VINCRISTINE 2mg/2ml 2ml Injection

- **Quantity:** **8100** vials
- **Delivery Time (weeks)** 8-12 weeks after approval
- **Price (VAT inclusive) per vial** R77,03 per vial
- **Generic Name:** VINCRISTINE Injection 2mg
- **Trade/Brand Name:** **VINCRISTINE** Injection
- **Packaging:** 1vial packed in 1's
- **Specifications:** **2mg** / **2ml 2ml** injection
- **Shelf-life:** 36 months
- **Package Insert:** Attached
- **Manufacturer:** Kwality Pharmaceuticals
- **Country of Origin:** 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

19 February 2025

QUOTATION # 20250220 V

TO: The National Department of Health

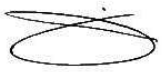
TEL: 012 395 0539
Email: Buhle.mbongo@health.gov.za

CONTACT PERSON / PATIENT: Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	PRICE INCL
VINC 001	Each vial contains 2mg / 2ml Vincristine Sulphate USP	1's	1	R66,98	R77,03
Brand		(packed in 1's)	**8100**	R542,538.00	R623,943.00
			Total	**R542,538.00**	**R623,943.00**

Valid for 90 days



Employee signature/s: _____

Date: 19 February 2025

Approved by: T Burger

Component : Carton
Dimension : 29 x 29 x 59 mm
Colour : CMYK
GSM : 320 gsm ITC Cyber XL
Coating: Drip off + Spot U.V.

Shelf Life : 36 Months

Checked with Dossier (Rohit)

Checked with Q.C. Dept.:

Check List for Labeling

Formulation No. :

Work Order 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
13433/1	English													
Matching all parameters between Box and Label														

Previous specimen artwork : NA	Designed by : SAJAN	Order Quantity	Party Name	Packing
		2000 VIALS	RAPHAEL	

Checked by :		Approved by :	Authorized by:	Party Approval
Production Incharge	QC Incharge	Q.A.	M.D.	

Card Board used for carton :

□ G/B □ W/B □ I.T.C. □ Pearl

Note : Since you have approved the artwork and did not implement our suggestion.

100 x 165 mm Front Back

For the use of cancer Hospital, Institution of Cancer Specialist only.

VINCRISTINE

Sulfate for Injection USP

2 mg/ vial

COMPOSITION:
Each vial contains :
Vincristine Sulfate USP 2 mg
Excipients ..... q.s.

DESCRIPTION: Vincristine Sulfate is the salt of a dimeric alkaloid isolated from a common flowering herb, the periwinkle plant (Vinca rosea Linn.). Although the mechanism of action has not been definitely established vincristine appears to inhibit microtuble formation in the mitotic spindle, resulting in an arrest of dividing cells at the metaphase stage.

INDICATIONS: Vincristine Sulfate is indicated in the treatment of acute; leukaemia, and as combination therapy with other oncolytic agents in the treatment of Hodgkins disease, non-Hodgkins malignant lymphomas (lymphocytic, mixed cell, histiocytic, undifferentiated, nodular and diffuse types), rhabdomyosarcoma, neruoblastoma and Wilms tumour.

PHARMACOKINETICS : Pharmacokinetics studies in patients with cancer have shown a triphasic serum decay pattern following rapid intravenous injection. The initial, middle and terminal half-lives are 5 minute, 2.3 hours, and 85 hours respectively; however, the range of the terminal half-life in humans is from 19 to 155 hours. The liver is the major excretory organ in humans and animals; about 80% of an injected dose of vincristine sulfate appears in the feces and 10% to 20% can be found in the urine. Within 15 to 30 minutes after injection, over 90% of the drug is distributed from the blood into tissue, where it remains tightly, but not irreversibly, bound.

DOSAGE AND ADMINISTRATION :
This preparation is for intravenous use only. Intrathecal use of the drug could be fatal.
Precaution for administration : Extreme care must be taken in calculating and administering the dose of Vincristine, since over dosage may have a very serious or fatal outcome. The solution should be withdrawn into an accurate dry syringe measuring the dose carefully. No extra fluid should be added to the vial in an attempt to empty it completely. The drug may be injected either directly into a vein or into the tubing of a running intravenous infusion. Injection of Vincristine Sulfate should be accomplished within one minute.
It is extremely important the intravenous needle or catheter may be properly positioned before Vincristine Sulfate is injected. Leakage into surrounding tissue during intravenous administration Vincristine Sulfate may cause considerable irritation. If extravasation occurs the injection should be discontinued immediately and the remaining portion of the dose should then be introduced into another vein. Local of hyaluronidase and the application of moderate heat to the area of leakage will help disperse the drug and may minimize discomfort and the possibility of cellulites.
The drug is to be administered intravenously at weekly intervals. in the presence of leukopenia, or a complicating infection, administration of the next dose of Vincristine Sulfate warrants careful consideration.

Adult : 1.4 mg/m^2
Children : 2.0 mg/m^2
For children weighing 10kg or less the starting dose should be 0.05 mg/kg once a week.

Impaired hepatic function: Vincristine Sulfate should not be given to patients while they are receiving radiation therapy through ports that include the liver.
In patients having a direct serum bilirubin value above 3mg/100ml the dose is reduced by 50 percent. Subsequent doses may be increased depending on tolerance to the initial treatment.
Patients Monitoring : Since dose-limiting clinical toxicity is manifested as neurotoxicity, clinical evaluation is necessary to detect the need for dosage modification. Following vincristine therapy some individuals may have a fall in the WBC and platelet count. Therefore a complete blood count should be done before each dose, as well as determine the serum uric acid levels during the first 3-4 weeks of therapy to prevent uric acid nephropathy.

CONTRAINDICATIONS : Demyelinating form of Charcot-Marie Tooth Syndrome.

Warnings and Precautions
DRUG INTERACTIONS:
L-asparaginase : Administering L-asparaginase before vincristine may reduce the hepatic clearance of the drug. Therefore when used in combination, vincristine should be given 12-24 hours before L-asparaginase administration to minimize toxicity.
Mitomycin C : Acute pulmonary reactions might occur on concomitant administration of mitomycin C.
Phenytoin : The simultaneous oral or intravenous administration of phenytoin and antineoplastic chemotherapy combinations that included vincristine sulfate has been reported to reduce blood levels of the anticonvulsant and to increase seizure activity. Dosage adjustment should be based on serial blood level monitoring. The contribution of vincristine sulfate to this interaction is not certain. The interaction mat result from reduced absorption of phenytoin and an increase in the rate of its metabolism and elimination.

Solvents : Vincristine Sulfate should not be diluted in solutions that raise or lower that pH outside the range of 3.5 to 5.5; it should not be mixed with anything other than normal saline.

PREGNANCY : There are no adequate and well-controlled studies in pregnant women. Vincristine can cause fatal harm when administered to a pregnant woman. If the drug is used during pregnancy or it the patient becomes pregnant receiving it, the patient should be apprised of the potential hazards to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

NURSING MOTHER: It is not known whether the drug is secreted in breast milk. Because of the potential for serious adverse reactions in nursing infants. a decision should be made on whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

IN IMPAIRED HEPATIC FUNCTION: See Dosage and Administration.

OTHERS: Acute uric acid nephropathy may occur.
CNS leukaemia has occurred in patients undergoing otherwise successful therapy with vincristine. If CNS leukaemia is diagnosed additional agnets may be required since this drug does not adequately cross the blood-brain barrier.
Particular attention should be given to dosage neurological side effects, if administered to patients with pre-existing neuromuscular disease.
Eye contamination should be avoided with concentration used clinically. If accidental contamination occurs server irritation may result. Eyes should be washed immediately and thoroughly.

SIDE EFFECTS: In general, adverse reactions to vincristine are dose-related and reversible. The most common adverse reaction is hair loss; the most troublesome adverse reactions are neuromuscular in origin.
When single weekly doses of the drug are employed, the adverse reactions of leukopenia, neuritic pain and constipation occurs but are usually of short duration. When the dosage is reduced the reactions may lessen or disappear. The severity of such reactions seems to increase when the calculated amount of drug is given in divided doses. Other adverse reactions, such as hair loss, paraesthesia, difficulty in walking, slapping gait, loss of deep tendon reflexes and muscle wasting may persist for at least as long as therapy is continued. Almost all symptoms usually disappears by about the sixth week after discontinuance of therapy. Some neuromuscular difficulties may persist for prolonged periods in some patients. Regrowth of hair may occur while maintenance therapy continues. The following adverse reactions have been reported.
Hypersensitivity or allergic type reactions : Anaphylaxis, rash.
Gastrointestinal : Constipation, abdominal cramps, nausea, weight loss, vomiting, oral ulceration, diarrhoea, paralytic ileus, intestinal necrosis and / or perforation and anorexia have occurred. All cases have responded to high enemas and lesatives.
Genito urinary : Polyuria, dysuria, urine retention due to bladder atony.
Cardiovascular : Hypertention and hypotension.
Haematologic : Serious bone marrow depression is usually not a major dose limiting event. However anaemia, leukopenia and thrombocytopenia have been reported.
Ophthalmic : Optic atrophy with blindness, transient cortical blindness, diplopia, photophobia.
Endocrine: Rare cses of syndrome attributed to inppropriate antiduretic hormone secretion have been observed. With fluid deprivation improvement occurs in the hyponatremia and in the renal loss of sodium.
Neurologic : Loss of deep tendon reflexes, foot drop ataxia and paralysis have been reported with continued administration. Myalgias have occurred. Severe pain in the jaw, pharynx, parotid gland, bone, back and limb.

OVERDOSE : Side effects are dose related. Therefore following administration of more than the recommended dose, patients can be expected to experience exaggerated side effects. Supportive care should include :
Prevnetion of side effects that result from the syndrome of inappropriate secretion of antidiuretic hormone
- Administration of anticonvulsants
- Use of enemas or cathartics to prevent paralytic ileus
- Monitoring the patients cardiovascular system and
- Daily blood counts for guidance in transfusion requirements.

DIRECTION FOR USE :
Reconstitute by adding 2ml of sterile Water for Injection

STORAGE : Store at temperature between 2°to 8°C. Protect from light. Do not freeze.
Keep out of reach of the children.

PRESENTATION : Each vial packed in a printed carton

Manufactured by:
Kwality Pharmaceuticals Ltd.
1-A, Industrial Area, Raja Ka Bagh, Tehsil -
Nurpur, Distt.- Kangra, (H.P.) - 176201. INDIA