



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 MITOMYCIN 2MG INJ

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

- **Mitomycin 2mg Injection**

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.

Section 21 Authorisation re Mitomycin 2mg INJ 30072026

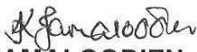
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, 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 **23 January 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	18
EC-PE	600
FS	300
GP	700
KZN	30
LP	0
MP	12
NC	3 600
NW	80
SAMHS	12
WC	200
Total	5552

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 31/7/2026

Section 21 Outcome Letter

2026-07-29

Ms Khadija Jamaloodien

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

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 **2026-07-23** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 10**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Mitomycin 2 mg**
- G. QUANTITY: 5544 Packs (10)**

H. LETTER NUMBER: S2100034229

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

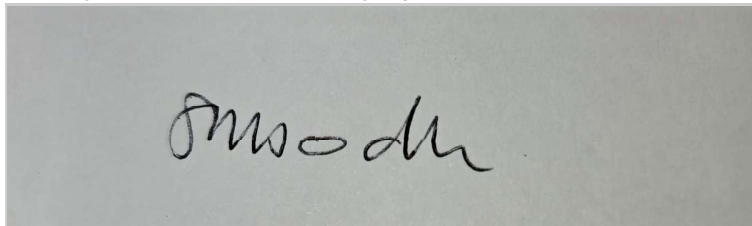
A progress report must be submitted once treatment is completed or on a reauthorization request

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 'Shyamli Munbodh' written in a cursive style.

Ms Mahlodi Moropa

Final Approver

S2100034229



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 and appears to be 'M. J. P.' or similar, written on a light-colored background.



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	S21RFQ179/2026
QUOTE ENQUIRY DATE	09/07/2026	QUOTE CLOSING DATE	16/07/2026	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)				

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo		
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za		
PHONE No.	066 261 4234	FAX No.	N/A

PRODUCT INFORMATION

DESCRIPTION PER MPC	Mitomycin 2mg Injection		
TRADE DESCRIPTION	Mitomycin Injection IP 2mg		
UNIT OF MEASURE	Vials	PACK or BOX (SIZE/ QUANTITY)	1 vial
QUANTITY REQUIRED	5 552		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

DID YOU BID ITEM FOR TENDER	YES		NO	x	IF NO, WHY	Section 21
COMPANY NAME	Equity Pharmaceutical (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	Hannes Strydom				
	PHONE	012 345 1747				

	MOBILE	082 616 1954	
	E-MAIL	hannes@equitypharma.co.za	
QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R 64.40	TOTAL PRICE (INCL. DELIVERY & VAT)	R 357 548.80
VOLUMES AVAILABLE – 14DAYS	5 552		
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE – 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
DEVIATION TO SPECIFICATION			
COMMENTS:			
DECLARATION BY SUPPLIER			
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 Medicines		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	2026/07/16		
PROVINCIAL ESTIMATES			
Province	Six Months Estimate		
DCS	0		
EC-MT	18		
EC-PE	600		
FS	300		
GP	700		
KZN	30		
LP	0		

MP	12
NC	3 600
NW	80
SAMHS	12
WC	200
Please submit quotations to Buhle.Mbongo@health.gov.za	

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

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- 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 supplier submitting the quotation must be the same entity 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.
- The confirmation letter from manufacturer to Supply South Africa with Bivalent oral Poliomyelitis Vaccine (bOPV) must be provided (only in cases of Bivalent oral Poliomyelitis Vaccine 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 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 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
- 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.

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



16/07/2026

National Department of Health

Directorate: Affordable Medicines

E-mail: 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

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

Dear Ms Mbongo

Re: Request for quotation – Mitomycin Injection 2mg – Section 21 Supply

Trust you are well. Please find below our quotation for Mitomycin Injection IP 2mg supplied under section 21 terms.

- Quantity: **5552 vials**
- Delivery Time (Weeks): **Lead time 1-2 weeks**
- Price (Vat Inclusive): **R 64.40 incl. vat per vial**
- Generic Name: **Mitomycin Injection 2mg**
- Trade Name: **Mitomycin Injection IP 2mg**
- Packaging: **1 vial**
- Specifications: **2mg / Vial**
- Shelf Life: **36 months**
- Package Insert: **Please find attached**
- Manufacturer: **Sakar Healthcare Limited**
- 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

16/07/2026



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 # 20260716

TO: National Department of Health

TEL : 012 395 9539

FAX :

Email : Section21Quotes@health.gov.za

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Mitomycin Injection IP 2mg	1 x Vial	1	R 56.00	R 64.40
			5552	R 310 912.00	R 357 548.80
	Lead time 7-14 days				
			5552	R 310 912.00	R 357 548.80

Valid for 180 days

Employee Signature: _____

Date: 16/07/2026

Approved by: Ehrard van Zyl

Other

Headache, blurring of vision, confusion, drowsiness, syncope, fatigue, edema, thrombophlebitis, hematemeses, diarrhea, and pain. These did not appear to be dose related and were not unequivocally drug related. They may have been due to the primary or metastatic disease processes.

WARNINGS

Patients being treated with Mitomycin Injection IP must be observed carefully and frequently during and after therapy.

The use of mitomycin Injection IP results in a high incidence of bone marrow suppression, particularly thrombocytopenia and leukopenia. Therefore, the following studies should be obtained repeatedly during therapy, platelet count, white blood cell count, differential, and hemoglobin. The occurrence of a platelet counts below 100,000/mm³ or a WBC below 4,000/mm³ or a progressive decline in either is an indication to withhold further therapy until blood count have recovered above these levels.

Patients should be advised of the potential toxicity of this drug, particularly bone marrow suppression. Deaths have been reported due to septicemia as a result of leukopenia due to the drug.

Patients receiving Mitomycin injection IP should be observed for evidence of renal toxicity. Mitomycin injection IP should not be given to patients with a serum creatinine greater than 1.7mg percents.

Usage In Pregnancy

Safe use of Mitomycin Injection IP in pregnant woman has not been established. Teratological changes have been noted in animal studies. The effect of Mitomycin Injection IP on fertility is unknown.

Nursing Mothers

It is not known if mitomycin is excreted in human milk. Because many drugs excreted in human milk and because of the potential for serious adverse reactions in nursing infants from mitomycin, it is recommended that nursing be discontinued when receiving mitomycin therapy.

PRECAUTIONS

Acute shortness of breath and severe bronchospasm have been reported following the administration of vinca alkaloids in patients who had previously or simultaneously received Mitomycin Injection IP. The onset of this acute respiratory distress occurred within minutes to hours after the vinca alkaloid injection. The total number of doses for each drug has varied considerably. Bronchodilators, steroids and/or oxygen have produced symptomatic relief.

A few cases of adult respiratory distress syndrome have been reported in patients receiving Mitomycin Injection IP in combination with other chemotherapy and maintained at FIO₂ concentrations greater than 50% perioperatively. Therefore, caution should be exercised using only enough oxygen to provide adequate arterial saturation since oxygen itself is toxic to lungs. Careful attention should be paid to fluid balance and overhydration should be avoided. Bladder fibrosis / contraction has been reported with intravesical administration (not an approved route of administration), which in rare cases has required cystectomy.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.
Storage: Store at a temperature not exceeding 25°C, protected from light.
Keep the medicine out of reach of children.

PRESENTATION

Mitomycin 2 is available in 10ml Vial.
Mitomycin 10 is available in 50ml Vial.
Mitomycin 40 is available in 100ml Vial.

Manufactured by:

Sakar Healthcare Ltd.

Block No. 426, Bavla-Bagodara Highway,
Village-Bavla, Dist.-Ahmedabad-382 220

Marketed by: **Zydus Lifesciences Limited**



Meto Inj PL-0824

For the use of a Registered Medical Practitioner or
a Hospital or a Laboratory only

Mitomycin for Injection IP

Mitomycin

WARNING

Mitomycin Injection IP should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

Bone Marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of Mitomycin injection IP.

Hemolytic Uremic Syndrome (HUS) a serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia, thrombocytopenia, and irreversible renal failure has been reported in patients receiving systematic Mitomycin Injection IP. The syndrome may occur at any time during systemic therapy with Mitomycin Injection IP as a single agent or in combination with other cytotoxic drugs, however, most cases occur at doses >60 mg of Mitomycin injection IP. Blood product transfusion may exacerbate the symptoms associated with this syndrome.

The incidence of the syndrome has not been defined.

Mitomycin 2

Each vial contains:
Mitomycin IP 2 mg

Mitomycin 10

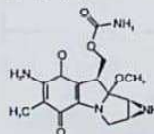
Each vial contains:
Mitomycin IP 10 mg

Mitomycin 40

Each vial contains:
Mitomycin IP 40 mg

DESCRIPTION

Mitomycin Injection is a sterile bluish violet lyophilized mass. It contains mannitol, water for injection as excipients. Mitomycin is an antibiotic isolated from the broth of *Streptomyces caespitosus* which has been shown to have antitumor activity. The molecular formula is C₁₅H₁₈N₄O₅ and its molecular weight is 334.33. Its structural formula is



CLINICAL PHARMACOLOGY

Pharmacodynamics

Mitomycin Injection IP selectively inhibits the synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content correlates with the degree of Mitomycin Injection IP - induced cross-linking. At high concentrations of the drug, cellular RNA and protein synthesis are also suppressed.

Pharmacokinetics

In humans, Mitomycin Injection IP is rapidly cleared from the serum after intravenous administration. Time required to reduce the serum concentration by 50% after a 30 mg bolus injection is 17 minutes. After injection of 30 mg, 20 mg, or 10 mg I.V., the maximum serum concentrations 2.4µg/ml, 1.7µg/ml, and 0.52 µg / ml, respectively. Clearance is affected primarily by metabolism in the liver, but metabolism occurs in other tissues as well. The rate of clearance is inversely proportional to the maximum serum concentration because, it is thought, of satisfaction of the degradative pathways.

Approximately 10% of a dose of Mitomycin injection IP is excreted unchanged in the urine. Since metabolic pathways are saturated at relatively low doses, the percentage of dose excreted in urine increases with increasing dose. In children, excretion of intravenously administered Mitomycin injection IP is similar.

INDICATIONS

Mitomycin is not recommended as a single-agent, primary therapy.

It has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Mitomycin is not recommended to replace appropriate surgery and/or radiotherapy.

CONTRAINDICATIONS

Mitomycin Injection IP is contraindicated in patients who have demonstrated a hypersensitive or idiosyncratic reaction to it in the past.

Mitomycin Injection IP is contraindicated in patients with thrombocytopenia, coagulation disorder, or an increase in bleeding tendency due to other causes.

DOSAGE AND ADMINISTRATION

Mitomycin should be given intravenously only, using care to avoid extravasation of the compound. If extravasation of the compound occurs, cellulitis, ulceration, and slough may result.

After full hematological recovery (see guide to dosage adjustment) from any previous chemotherapy, the following dosage schedule may be used at 6 to 8 week intervals: 20mg/m² intravenously as a single dose via a functioning intravenous catheter.

Because of cumulative myelosuppression, patients should be fully reevaluated after each course of Mitomycin Injection, IP and the dose reduced if the patient has experienced any toxicities. Doses greater than 20mg/m² have not been shown to be more effective and are more toxic than lower doses.

Guide to dosage adjustment:

Nadir after prior dose Leucocyte/mm ³	Platelets / mm ³	Percentage of prior dose to be given
>4000	>100,000	100%
3000-3999	75,000-99,999	100%
2000-2999	75,000-99,999	70%
<2000	<25,000	50%

No repeat dosage should be given until leucocyte count has returned to 4000/mm³ and a platelet count to 100,000/mm³. When Mitomycin injection IP is used in combination with other myelosuppressive agents, the doses should be adjusted accordingly. If the disease continues to progress after two courses of Mitomycin Injection IP, the drug should be stopped since chances of response are minimal.

Reconstitution:

Each vial contains Mitomycin 2mg, 10mg and 40mg. To administer, add Sterile Water for Injection, 4ml, 20ml and 80ml respectively. Shake to dissolve. If product does not dissolve immediately, allow to stand at room temperature until solution is obtained.

Stability

1. Unreconstituted Mitomycin injection IP stored at room temperature is stable for the lot life indicated on the package. Avoid excessive heat (over 40°C, 104°F).

2. Reconstituted with Sterile Water for Injection to a concentration of 0.5 mg per ml, Mitomycin injection IP is stable for 14 days refrigerated or 7 days at room temperature.

3. Diluted in various I.V fluids at room temperature, to a concentration of 20 to 40 micrograms per ml.

I.V Fluid	Stability
0.9% Sodium Chloride Injection	12 hours
Sodium Lactate Injection	24 hours

The combination of Mitomycin Injection IP (5mg to 15mg) and heparin (1,000 units to 10,000 units) in 30mL of 0.9% Sodium Chloride Injection is stable for 48 hours at room temperature.

Overdosage

No data is available

ADVERSE REACTIONS

Bone Marrow Toxicity

This was the most common and most serious toxicity. Thrombocytopenia and / or leukopenia may occur anytime within 8 weeks after onset of therapy with an average time of 4 weeks. Recovery after cessation of therapy was within 10 weeks. Mitomycin Injection IP produces cumulative myelosuppression.

Integument and Mucous Membrane Toxicity

This had occurred in approximately 4% of patients treated with Mitomycin Injection IP. Cellulitis at the injection site has been reported and is occasionally severe. Stomatitis and alopecia also occur frequently. Rashes are rarely reported. The most important dermatological problem with this drug, however, is the necrosis and consequent sloughing of tissue which result if the drug is extravasated during injection. Extravasation may occur with or without an accompanying stinging or burning sensation and even if there is adequate blood return when the injection needle is aspirated.

Renal Toxicity

2% of 1,281 patients demonstrated a statistically significant rise in creatinine. There appeared to be no correlation between total dose administered or duration of therapy and the degree of renal impairment.

Pulmonary Toxicity

This has occurred infrequently but can be severe and may be life threatening. Dyspnea with a nonproductive cough and radiographic evidence of pulmonary infiltrates may be indicative of Mitomycin Injection IP-induced pulmonary toxicity. If other etiologies are eliminated, Mitomycin Injection IP therapy should be discontinued. Steroids have been employed as treatment of this toxicity, but the therapeutic value has not been determined.

Hemolytic Uremic Syndrome (HUS)

This serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia (hematocrit < 25%), thrombocytopenia (< 100,000/mm³), and irreversible renal failure (serum creatinine > 1.6 mg/dL) has been reported in patients receiving systematic Mitomycin Injection IP. Microangiopathic hemolysis with fragmented red blood cells on peripheral blood smears has occurred.

Other less frequent complications on the syndrome may include pulmonary edema, neurologic abnormalities and hypertension. Exacerbation of the symptoms associated with HUS has been reported in some patients receiving blood product transfusions. A high mortality rate has been associated with this syndrome.

The syndrome may occur at any time during systematic therapy with Mitomycin injection IP as a single agent or in combination with other cytotoxic drugs. Less frequently, HUS has also been reported in patients receiving combinations of cytotoxic drugs not including mitomycin injection IP. Patients develop the syndrome at total doses exceeding 60mg of Mitomycin injection IP. Consequently, patients receiving >60mg of Mitomycin injection IP should be monitored closely for unexplained anemia with fragmented cells on peripheral blood smear, thrombocytopenia, and decreased renal function.

The incidence of the syndrome has not been defined. Therapy for the syndrome is investigational.

Cardiac Toxicity

Congestive heart failure, often treated effectively with diuretics and cardiac glycosides, has rarely been reported. Acute side effects due to Mitomycin Injection IP were fever, anorexia, nausea, and vomiting.

Acute Side Effects Due to Mitomycin were fever, anorexia, nausea, and vomiting. They occurred in about 14% of 1,281 patients.

zydus

R_x
Mitomycin
for Injection IP
2 mg / Vial

Mitomycin 2

For I.V. Infusion after Dilution

Single Use Vial

Lyophilized

2 mg/Vial

**2
mg**

R_x

Mitomycin for Injection IP 2 mg / Vial

Mitomycin 2

मिटोमायसिन २

Each vial contains:

Mitomycin IP 2 mg

Store at a temperature not exceeding 25°C,
protected from light.

Dosage: As directed by an Oncologist.

Keep the medicine out of reach of children.

Please refer accompanying package
insert for detailed dosage, directions
for use and precautions.

SCHEDULE H PRESCRIPTION DRUG- CAUTION:
Not to be sold by retail without the prescription of
a Registered Medical Practitioner.

Warning: Cytotoxic Agent- To be sold by
retail on the prescription of an Oncologist/
Cancer Hospital/ Institution only.

CAUTION: This injection should not be
used if it contains visible particulate matter.
Do not use if cloudiness or precipitate is
observed.

Batch No. : SKI26020A
Mfg. Date : MAR2026
Expiry Date : FEB2028
Maximum
Retail Price ₹ : 234.30
(Inclusive of
All Taxes)

Mfg. Lic. No.: G/28/1865

Manufactured by:
Sakar Healthcare Ltd.
Block No. 426, Bavla – Bagodara Highway,
Village-Bavla, Dist.-Ahmedabad-382 220

Marketed by:
Zydus Lifesciences Limited
Zydus Corporate Park, Scheme No. 63,
Survey No. 536, Khoraj (Gandhinagar),
Near Vaishnodevi Circle,
Ahmedabad, Gujarat -382481.

Meto2 Inj CT-0824



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